Study on the Value of Medical Devices in Germany

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Preface

Twenty years ago, we could not have imagined the phenomenal ways in which computer technology and the internet have made our lives more enjoyable and productive. Today, we stand at the brink of a similar revolution in medical diagnostics and treatment if we maintain an open system for medical innovation.

Medical technology plays a central role in the delivery of high quality, affordable health care especially if there are multiple ways to assess and access it. Every day, innovative medical technologies capable of diagnosing, preventing and treating diseases are discovered, such as routine screening during pregnancy and early detection of infectious diseases. In an era of aging populations, medical innovations can improve the quality of peoples’ lives, lower the societal costs of stress, unemployment and disabilities, and increase the efficiency of health care systems and economic growth. Technological advancement is part of the solution and the future in Germany!

The medical industry comprises highly talented and entrepreneurial physicians, engineers, and researchers who continuously seek solutions to health care problems. It is a truly dynamic industry that is represented by hundreds of relatively small firms. While most medical innovation is often incremental, this innovation process leads, over time, to fundamental improvements in health care within the right policy environment. Industry's efforts in this regard help German patients enjoy access to the best available medical technologies; help the German health care system allocate its resources wisely and efficiently; and contribute enormously to the German economy through exports and jobs.

Like the information technology industry, and unlike the pharmaceutical industry, relatively small firms are the backbone and an important source of innovation in the medical technology industry. This industry invests enormous time and resources to bring promising new innovations to patients. On average, medical device manufacturers invest 10% of their revenues in research and development activities.

All medical devices must undergo rigorous tests of their safety and efficacy and are increasingly subject to technology assessment. Increasingly, they are subject to technology assessment. While important, these reviews can have adverse effects on the fragile chain of innovation if they are not conducted appropriately. In particular, such review procedures must be transparent and expeditious. Furthermore, the decisions made in the course of review procedures must be subject to legal recourse. Patients and manufacturers must also be granted the right to participate in these decision-making procedures. Otherwise, patients will be denied access to the best available medical technologies, and there will be less incentive for industry to develop and market even better technologies for future patients.

Typically, more than 50 percent of medical device firms' revenues stem from devices that are less than two years old. The demand for new ideas and superior therapies is immense and so is the medical technology industry’s commitment to Germany. The following study highlights existing problems related to German patients' access to the latest medical devices and puts forth realistic solutions to these problems.
Executive Summary

Medical devices and medical technology play a central role in all sectors of the German health care system: in prevention, diagnosis, treatment and rehabilitation. From simple wound dressings to modern incontinence products, from fever thermometers to magnetic resonance imaging, from hearing aids to cardiac pacemakers and from home pregnancy tests to sophisticated laboratory systems, medical devices are indispensable in the provision of modern, high-quality health care.

The present study was commissioned by a working group of internationally active medical device manufacturers. It describes the economic value and medical benefits of modern medical technology. It also seeks to raise public and political awareness of the need for conditions that foster continued innovation as a means for maintaining and improving the level of health care in Germany.

The quality and finance of modern medical care

Health care policy in Germany is aimed at providing a high level of health care to all members of society. There is a broad consensus on this objective. Health is a highly valued "good" and German patients have benefited from the country’s highly developed health care system and from advances in medicine and medical technology. All Germans presently have equal opportunity - independent of their financial means and social status - to receive the most modern medical treatment such as minimally-invasive surgical procedures, a heart valve, a hip prosthesis or an inner ear prosthesis.

Of course, such high quality health care must be financed. With a share of only 10 percent, medical devices make up only a small portion of total expenditures in Germany’s Social Health Insurance system. Yet some people believe that new medical technology is a decisive factor in increasing health care expenditures. Given that the vast majority of the German population has a very positive view of medical devices and supports the application of technical advances in medicine, the present study is concerned with the following questions:

How can we ensure that reasonable and necessary medical devices and procedures remain available to the population in general?
The Value of Medical Devices in the German Health Care System

Executive Summary

How can new and improved medical devices and medical procedures be introduced into the German health care system without avoidable delays?

The study does not focus on the general financial problems of Germany’s health care system. Rather, it is intended to initiate a broad discussion on the structure and quality of the health care system as a basis for deciding what society is willing to pay to maintain a high level of health care. Then a decision can be made as to how much society is willing to pay for health. However, in light of the growing need for health care services, it is unlikely that the share of health care expenditures in gross national product will decrease or even remain constant. The aging of the population, the increasing prevalence of chronic degenerative diseases and co-morbidity as well as changing preferences will require tapping new sources for the funding of health care. According to a recent survey, the majority of Germans desire the best possible medical care even if they have to pay more for it.²

The provision and finance of health care in the hospital sector

Germany’s hospital sector is acknowledged as one of the most advanced in the world. Modern medical technology and medical know-how are available to the whole population. The hospital sector is also the largest single cost factor in the German health care system. Many observers believe that there is enormous potential for increasing the efficiency of hospital care. Reform proposals focus on the system for the funding and reimbursement of hospital services. However, past reform have been only partially successful in improving the economic performance of hospitals. At present, approximately 75 per cent of all hospital services are financed on the basis of per diem fees.

The implementation of mechanisms and structures that reduce hospital length of stay can play an important role in cutting costs and improving efficiency in the hospital sector. However, in many cases, the current system of hospital finance does not “reward” the application of new procedures, e.g. minimally-invasive surgery, and thus tends to hinder innovation.

The introduction of a comprehensive system based on "Diagnosis Related Groups" (DRGs) as called for under the health care reform enacted at the beginning of 1999 represents a step in the right direction. However, the system, which is scheduled to be
introduced in 2003, must ensure that hospital services are paid for at levels that adequately reflect the quality and content of the services provided.

In the preparation and design of the new system for funding hospital services on the basis of a DRG system, it is particularly important that

- decisions are made on the basis of a constructive dialogue involving all affected interests,
- the elements of the new system (e.g. diagnostic groups, relative values and costing weights) are well specified and differentiated and adjusted to reflect the situation in Germany,
- the system ensures the rapid adjustment to medical and technological progress on a regular basis,
- the new reimbursement system is essentially a flexible pricing system for hospital services.

It is likely that strict budget limits on hospital spending will remain in effect until the new system of hospital finance is implemented in 2003. Since hospital budgets are based on revenue trends in the Social Health Insurance system and not on medical needs, they tend to stifle innovation. Health policy experts agree that the implementation of separate budgets in each sector also tend to limit innovation. It is up to the partners in Germany’s system of “joint self administration” and especially the SHI funds to ensure that the budget limits do not keep medical progress out of German hospitals and doctors’ practices. The study’s recommendations therefore focus on reforms of the existing system and the planned system that would increase the transparency of the decision-making procedures, the accountability of decision-makers, and the participatory rights of medical device manufacturers and patients.

The introduction and diffusion of medical devices in the German health care system

In the course of recent health care reforms, Germany’s lawmakers have increasingly resorted to measures that hinder the introduction and diffusion of new medical devices in the health care system. As a result, patients in Germany may not always benefit from advances in diagnosis and therapy. Health insurers and in particular the social health insurance funds often refuse to cover procedures that they do not consider to be
standard medical practice, thereby delaying the potential medical and economic benefits of new technologies. But who decides what standard medical practice is and what are the criteria on which such decisions are based? Although there is a general consensus in Germany on the need for increased efficiency in the health care system, there are currently few approaches for promoting the systematic analysis of the cost effectiveness of new medical devices. Even payers are reluctant in this respect, so that efforts to create a consensual basis for reimbursement decisions have had little impact on actual decision-making processes.

Since 1989, the medical and economic benefits of new diagnostic and therapeutic procedures must be documented and are subject to review at national level before the procedures can be subject to general coverage in the office-based sector. This review process and the ensuing decision making process are the responsibility of a committee (“Medical Procedure Committee”) and a committee for the valuation of medical procedures (“Fee Schedule Committee”).

Unfortunately, in the present policy environment, the procedures for the review and pricing of innovative medical procedures have proven to be very long and resulted in many unwarranted negative decisions. Furthermore, the decision making process lacks transparency. To facilitate the introduction of the new procedures in the office-based sector, the study makes the following recommendations:

- The transparency of the decision-making process should be increased.
- The review of new diagnostic and therapeutic procedures should be conducted as rapidly as possible and completed within specified time frames.
- The fusion of the two national committees as means for expediting and rationalizing the review process for new and existing diagnostic and therapeutic procedures.
- The right to submit products and procedures for review and to participate in the review process should be extended to all affected interests, i.e. patients and manufacturers.
The legislation implemented at the beginning of 2000 calls for the establishment of a similar procedure for the review of medical procedures in the hospital sector. In light of the plans to introduce a system of hospital payments based on DRGs, such a committee is unnecessary and will place additional restraints on hospitals. If such a committee is established as a means for cementing "command and control" measures in the hospital sector, then it is recommended that the committee be established on the basis of the following principles:

- The evaluation procedure should be quick, transparent, flexible and based on objective criteria of technology assessment.
- Introduction of a clearly defined process for the review of new diagnostic and therapeutic procedures that allows for manufacturers' and patients' input and specifies time frames for the conclusion of decisions.
- Contracts at local/regional level (i.e. with individual hospitals and SHI funds) should remain possible.
- Local clinical studies should be covered on the basis of provisional reimbursement agreements.
- National and international experience in the application of the procedures in question should be taken into consideration in the review process.

The study’s conclusions point out that technology review procedures based on these recommendations can help ensure that the health care system remains open to innovation and continue to provide high quality and safe medical devices to patients in the future.

**Medical devices: The perception of decision-makers in the German health care system**

Part of the study was a perception survey of 23 decision-makers and opinion leaders in the German health care system; it was conducted between August and December 1999. The interviewees included representatives of political parties, social and private health
insurance organizations, healthcare providers and patient groups. The interviews were designed to elicit views on medical devices, the medical device industry, and its role in health care.

The interview process was not designed as a representative survey. Rather, it was designed to provide insight into the knowledge, views and opinions of key decision-makers and opinion leaders. In general, the interviewees were well informed with respect to medical devices and medical device manufacturers. They acknowledged the role of new medical devices in helping to save lives and improve the quality of life. Paradoxically, many respondents felt that the advances represented by medical devices represent only marginal improvements.

The survey results also indicate that decision-makers expect reliable evidence of medical benefits and, increasingly, technology assessment to demonstrate medical benefits cost effectiveness of new products and procedures.

Most decision-makers believe that there is no need to expand the rights of medical device manufactures in the review processes of medical procedures and devices. These results reveal an obvious need for heightening decision-makers' awareness of existing problems (e.g. lack of transparency, a monopolistic decision-making structure, slow decision-making processes, legal uncertainty) and of the adverse consequences of these problems (e.g. patient access delays, reduced incentives to introduce new innovations).

**Case studies: Medical devices and medical progress**

Examples that demonstrate the enormous advances in medicine and in the area of medical devices abound. The German weekly “Der Spiegel” wrote that "the 20th century has brought more medical advances than all the rest of human history since the Neanderthal Man" and "without the medical device industry there would be no medical progress."

Path-breaking innovations have been made in all product groups, from the so-called "commodities" sector (e.g. medical dressings) to the area of complex medical equipment, and by all types of companies (e.g. small niche companies, medium-sized companies and international corporations).

Laboratory tests, for example, provide valid and quantifiable information that is central to definitively diagnosing a disease, monitoring and quantifying a therapy, improving patient compliance and providing a rational basis for rehabilitation. As the case studies
of laboratory diagnostics demonstrate, the appropriate utilization of these medical devices provides information that can be used to benefit patients and to save considerable costs in other areas of the health care system.

Implantable cardioverter defibrillators (ICDs) provide an example of new medical devices that offer cost-effective means of treating serious and often fatal heart conditions. The ICD is a device which detects and treats abnormally fast heart rhythms. Advances in medical technology have made it possible to identify and treat patients with a high risk of life-threatening cardiac rhythm disturbances. Even with high-risk patients in whom spontaneous arrhythmia episodes have not yet occurred, ICD therapy has proven to be a very effective means of prevention.

Although the term “apparatus medicine” is often used to criticize trends in modern medicine, the role of innovative medical devices in improving health care is undisputed. Innovative medical devices and new medical procedures provide new diagnostic and therapeutic alternatives. Progress is not only felt by patients; it is also measurable in higher survival rates, increased life expectancy and better quality of life.

The case studies also demonstrate how medical devices increase efficiency in the provision of health care and help maintain the stability of health insurance contribution rates in Germany. Contrary to the view that society is bound in a "progress trap" and medical technology contributes considerably to cost increases in the health care system, innovative medical devices provide a basis for cost effective or cost neutral progress. The rational application of advances in medical technology frequently leads to clear savings in the treatment and diagnosis of disease. At the same time, new diagnostic and therapeutic procedures for the treatment of diseases for which there was no previous means of identifying and treating the disease will cost additional money. Yet these advances will also save lives. One way around this problem is rationing, which no one in Germany desires. The solution should include the provision of the necessary funding for these services.

The case studies underscore the important contribution of medical devices as vehicles of technological progress. They show the enormous benefits that medical devices bring to patients and their potential for increasing efficiency in health care. However, due to the existing structures and mechanisms in the German health care system, this potential is often not realized. The case studies are therefore used to illustrate the hurdles that all new and innovative procedures must overcome before they can be made available to all patients. The study’s recommendations outline the steps that must be taken to realize
the benefits of advances in medical technology and to enhance quality and effectiveness in the provision of health care.


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1 Introduction

Medical devices play a key role in all sectors of the German health care system: from prevention and diagnosis to treatment and rehabilitation, from a simple band-aid to modern wound care products, from a fever thermometer to a magnetic resonance imagining device, and from a home pregnancy test to a sophisticated laboratory assay: Medical devices make a significant contribution towards improving patients' health and in the provision of health care.

The German news magazine "Der Spiegel" wrote that "the 20th century has brought more medical advances than all the rest of human history since the Neanderthal Man" and "without the medical device industry there would be no medical progress."1

Groundbreaking innovations have been made in all product groups, from the so-called "commodities" sector (e.g. medical dressings) to the area of complex medical equipment, and by all types of companies: small niche companies, medium-sized companies and international corporations.

Innovation in the area of medical devices has made important contributions to improving the quality and effectiveness of health care. Innovative medical devices create new diagnostic and therapeutic opportunities. The results of medical innovation are tangible and measurable as better survival rates, longer life expectancy and improved quality of life.

The prime objective of medical devices is to contribute to the diagnosis and treatment of the sick and to protect the healthy from disease. However, medical devices also play an important role in increasing the efficiency of the health care system and thus contribute to the stabilization of social security contribution rates.

Despite the popular belief that we are caught in a "progress trap" in which new medical devices leads to spiraling health care costs, innovative medical devices are often cost effective or cost neutral. Furthermore, in many cases, it can be shown that the rational implementation of medical advances can lead to a considerable savings potential.

In the past, the results of medical and technological progress have been made available to patients insured under Germany's social health insurance system as long as they represented medically necessary and cost effective alternatives.

Through recent health care reforms, measures have been introduced that increasingly hinder patients' access to newer and more effective forms of diagnosis and therapy. As a result, the potential benefits of technological advances to patients are not realized and the potential cost advantages for payers are left unutilized.
Although there is a general consensus in Germany regarding the need for increased efficiency in the health care system, there are currently few approaches for promoting the systematic analysis of the cost effectiveness of new medical devices. Even payers are reluctant in this respect, so that efforts to create a consensual basis for reimbursement decisions, such as evidence-based medicine, have had little impact on actual decision-making processes.

Recommendations such as that of the Advisory Council for Concerted Action in Health Care, which call for the close co-operation of health care providers, payers and manufacturers, have fallen largely on deaf ears. The requirement that SHI funds act "collectively and uniformly" (gemeinsam und einheitlich) with respect to benefits blocks competitive strategies of SHI funds based on the coverage of new procedures either as standard or optional benefits.

Innovative products and medical procedures must overcome numerous hurdles before they are subject to coverage under the social insurance system. The social insurance carriers and in particular the social health insurance (SHI) funds may refuse to cover new and innovative procedures that - due to their "newness" - have not yet become part of standard medical practice. But who decides what standard medical practice is and what are the criteria on which such decisions are based?

In the case of much-needed innovations, it is often necessary to avoid a vicious circle: the greater the effort needed for successful market introduction and the greater the resistance of conservative medical professionals, the greater are the costs for the innovative manufacturers. As a result, the dedication of resources to research and development tend to decline, and the rate of innovation declines.

The development of innovative medical technologies requires considerable research effort and large investments. By the time a device can be put on the market, has undergone clinical trials and is covered by the SHI system, the break-even point is often much later in the product life cycle than in other sectors.

The question that must be answered is therefore: How can we ensure that advances in medicine and medical device technology remain accessible as early as possible and to as many patients as possible?

The present study is an attempt to provide answers to this question. The primary focus is not on the general financial problems of the German health care system. Instead, the study focuses on providing examples for the value of medical devices in health care and the hurdles to the introduction of new medical devices in Germany's health care system. Based on this information,
The study lists recommendations for improving patients' access to the fruits of research in the area of medicine and medical devices.

2 Medical Devices in the German Health Care System

2.1 Definition

Under the German Medical Device Act (MDA), medical devices are defined as any instrument, apparatus, appliance, material, or other article, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- contraception.

The products that fulfill these and other more detailed criteria have played an important role in improving general health status in Germany, increasing longevity and improving the quality of life.

Price competition, in part due to the price controls of SHI funds, has played an increasing role in medical device markets. Nonetheless, these markets are driven primarily by innovative competition with new products, new applications and improved quality. This requires strong research and development activity. On average, the German medical device industry puts 10 per cent of its sales back into the research and development of new technologies.

2.2 What are medical devices?

The term medical devices encompasses a wide range of products:

- Medical products in the sense of the German Social Code/Book V, such as nursing care products, stoma and incontinence products, hearing aids, eyeglasses, wheelchairs, etc,
- Products such as medical dressings and surgical materials,
- Active implantable medical devices such as pacemakers, medication pumps, inner ear prostheses and implantable cardioverter defibrillaters (ICDs),
- Electromedical equipment such as respiratory devices,
- Technical instruments and products such as surgical utensils, etc.,
- Dental products,
- In vitro diagnostics.
Medical devices differ from pharmaceuticals in that their effects on the body are produced primarily by physical (mechanical or electrical) and not pharmacological means.

2.3 The role of the CE mark

In order for a medical product to be marketed in the European Union it must have a CE mark. The CE mark is a seal of quality for a product that meets legally required specifications with regard to safety, performance and quality. The CE mark documents that a medical product is in compliance with the essential requirements of the EU guidelines and the MDA and that this has been proven in a conformity assessment procedure. The fulfillment of these comprehensive legal requirements guarantees a high level of health protection, performance and safety for patients, health care providers and third parties.

For the individual manufacturer, this has a number of implications with respect to each medical device.

- In terms of safety and risks:
  - The analysis and evaluation of safety and risks
  - The minimization of side effects
  - Proof that the product is biologically compatible
  - Proof of electronic and mechanical safety
  - The safety of use in combination with other products
  - The compilation of complete and comprehensible instructions.

- In terms of performance and benefits it implies:
  - Adherence to manufacturer's claims
  - Securing therapeutic benefits
  - The avoidance of contamination and infections
  - The appropriate clinical evaluation of the product
  - Ensuring the accuracy of the product

- In terms of monitoring it implies:
  - The vigilance of the manufacturer
  - Performance of a product over the whole life cycle of the product.
2.4 Where are medical devices used?

Medical devices are used in all sectors of the health care system: in hospitals, in doctors’ offices, and at home by patients.\textsuperscript{1}

The hospital market represents the most important market for the some 1,200 medical device manufacturers in Germany. In 1997, German hospitals spent DM 15.4 billion on medical supplies, most of which was for the purchase of medical devices (approximately DM 3.7 of this amount was spent on pharmaceuticals). For the year 2000 it is expected that Germany’s hospitals will spend at least DM 15 billion on medical devices.

In the ambulatory sector, the market for medical devices is estimated by BVMed to be approximately DM 10 billion, so that the total market for medical devices in Germany is more than DM 25 billion\textsuperscript{2}, or approximately 10 per cent of total national health care expenditures.

It is anticipated that patient co-payment for medical devices, as well as over-the-counter sales of medical devices, will grow considerably in the future.

2.5 The medical device industry in the German economy

Due to its high wage levels and high rates of taxation and charges, Germany has lost some of its attractiveness as a site for industry. Still, on the basis of its educational system and infrastructure, Germany has a large number of highly qualified workers who compensate for the costs of labor and ancillary wage costs with their high productivity. However, individual productivity is of little use if the appropriate industries are not present to utilize this potential in the creation of high-quality products.

Medical device manufacturers contribute to maintaining and improving Germany’s role as a supplier of modern and innovative medical devices and thus strengthen Germany's international competitiveness.

2.5.1 Production, employment and industry structure

Precise estimates of the total output of the German medical device industry are difficult to make due to the wide and diverse range of medical devices and the many medical device manufacturers. According to the calculations of the Advisory Council for the Concerted Action in Health Care, the production volume of the medical device manufacturers in Germany in 1996 was in the range of DM 27-29 billion. This represents approximately 14 per cent of the world market for medical devices.
The medical device industry in Germany is made up of approximately 1,200 manufacturers that provide employment to 110,000 skilled workers and professionals. The share of salaried employees in the total number of employees varies between 36 and 46 per cent according to branch of the medical device industry and is clearly above the average for manufacturing industries as a whole (35 percent).

The majority of medical device manufacturers are small to medium-sized companies. According to the data of the German Statistics Office, more than two thirds of the manufacturers of medical equipment and orthopedic devices have fewer than 50 employees and 86 per cent have fewer than 100 employees (Figure 2.1). Since this data includes only companies with 20 employees or more, the share of small companies is actually even greater.

Figure 2.1  Medical device manufacturers according to the number of employees

In terms of sales volume, however, the role of small and medium-sized manufacturers is relatively small. Manufacturers with fewer than 100 employees are responsible for approximately 28 per cent of sales volume. Companies with more than 500 employees produce nearly half of the sales volume (Figure 2.2).
2.5.2 Medical devices as an export factor

Germany’s medical device industry makes an important contribution to the export surplus. The total value of medical device exports was DM 13 billion in 1998. A significant share of Germany’s medical device exports (over 60%) goes to countries outside of the European Union and thus helps strengthen the European currency.

Examples of branches in which the rate of exports is particularly high are provided in Figure 2.3. The importance of markets outside the European Union is particularly evident for the manufacturers of the medical devices shown in the figure. The strong export performance of the medical device industry, which benefits both the German and the European economy, is especially evident in the areas of “contrast media and laboratory diagnostics”, “photofluorography and radiation therapy equipment”, and magnetic resonance tomography “MRT”.

Figure 2.2  Share in production volume according to number of employees

Source: Statistisches Bundesamt, Fachserie 4, Reihe 4.3, July 1999
Although medical device manufacturers employ less than 0.5 per cent of Germany’s labor force, their share in German exports is 1.4 per cent. The medical device industry thus makes a considerable contribution not only to the German economy, but also to the stability of the European currency.

### 2.5.3 Research & Development

Research and development of innovative products play a central role in the medical device industry. Due to the increasing costs of research and development, shorter product life cycles and a frequent long period until market introduction, the risks associated with research have also grown.

According to a study conducted for the European Commission, the European medical device industry invests roughly 5 per cent of its sales volume in the research and development of new products. For Japan and the USA, these figures are somewhat higher, at 6.7 and 6 per cent. According to the Advisory Council for Concerted Action in Health Care, the leading role of the German medical device industry is reinforced by the fact that it invests 10 per cent of its sales volume in research and development.

2 Bundesfachverband der Arzneimittel-Hersteller e.V. (Hrsg.). Medizinproduktebuch. Unkel, 1999


3 The provision and finance of health care in Germany

3.1 The hospital sector

3.1.1 Hospital services and trends in the hospital sector

The German hospital system has a high international standing. Innovative technologies and the modern medical procedures are provided in the hospital sector and are fully accessible to patients. Approximately 89 per cent of the population is covered by Germany's Social Health Insurance (SHI) system. Commercial health insurers privately insure another 9 per cent.

Hospital supply in Germany has been characterized for years by a steady reduction in capacity. A considerable part of the total reduction of approximately 94,000 beds (representing a 14% decrease) between 1991 and 1998 was due to the reduction in the size of existing hospitals. However, approximately 200 hospitals were closed or converted into other facilities.

Although the number of hospital beds decreased during the 1990s, the number of the cases treated in the hospital sector increased over the same period by 2.1 million (+15%). The hospital sector could deal with the growth in the number of cases because at the same time the average length of stay decreased by approximately 27 per cent (-3.9 days). This reduction in the length of stay more than compensated for the increase in the number of cases, so that the total volume of "patient days" decreased (-32.9 million days or -16%). The following figure provides an overview of these trends. The trends depicted represent an improvement in hospitals' efficiency, which allows hospitals to provide more treatment with fewer beds. To a great extent, these improvements were realized through the use of innovative medical products that allow for less invasive treatment.
The continuation of these trends in the number of cases, total number of days of hospital treatment and the length of stay are expected to continue in the future. The average length of stay in German hospitals will thus approach the lower levels already reached in other countries.

In 1998 the hospital sector in Germany comprised a total of 2,263 hospitals. Total hospital capacity was approximately 572,000 beds. More than 16 million patients were treated over a total of 170.6 million in-patient days. The average length of stay was about 10.7 days. The rate of hospital utilization equaled 81.9 per cent. Altogether approximately 1.1 million persons were employed in the hospital sector, resulting in an annual salary of DM 110 billion.
In contrast to a free market system, it is not the patient (as the "consumer") but their health insurer that pays for health care in Germany. There is not yet broad acceptance of patient cost sharing as an instrument for increasing patient self-responsibility. Patients therefore have little or no incentive to demand less costly services. From the patient's point of view, the "best possible" treatment is always the preferred alternative.

The rise in demand for health care is also due to the fact that individual demand for "health" increases faster than income - a phenomenon that can be observed in all wealthy industrialized countries. In time, it will be necessary to find new ways to tap new sources of funding. This necessity will arise in large part because of the hospital sector, which is already the greatest single expense item of the private and social health insurers in Germany. During the late 1990s, expenditures on hospitals also grew faster than expenditures on the other sectors.

### 3.1.2 The system of dual hospital finance

The hospital finance system in Germany is referred to as "dual" because it distinguishes between the funding of capital costs and the funding of operating costs. The basic principles of this system were set down in 1972, in the Hospital Finance Law. A schematic representation of the hospital finance system is shown in the following figure.
Under the system of dual hospital finance, the funding of capital costs is the responsibility of the states. Funding comes from tax proceeds and is allocated according to each state's hospital plan. Operating costs are financed by the health insurance funds. From 1972 to 1995, the law required full coverage of the operating costs of hospitals through the social and private health insurance funds. Since 1996/97, the law calls for a "service-based" reimbursement of hospitals.

Rising expenditures as a result of more treatment possibilities and more complex treatment options in the hospital sector coupled with the slow growth of the SHI system's revenues increased pressure for the reform of the social health insurance in the mid-1980's. As the first in a series of cost-containment laws, the German Bundestag passed the Hospital Reform Law (KHNG) in 1984 and an amended version of the Hospital Rate Ordinance (BPflV ) in 1985.

Like the laws that followed it, the KHNG succeeded in slowing expenditure growth only for a short period. This is reflected in the growth of the average SHI contribution rate from 11.9% in 1981 to 13.6% in the first half of 1999.
In order to avoid further increases in the average SHI contribution rate, lawmakers wrote the principle of stable contribution rates into social security law (SGB V) in 1988. According to the law, the per capita expenditures of the SHI funds may rise only to the extent that the assessable income of the paying members also rises.

The economic background for this was - and still is - the fear of unemployment. Rising SHI contribution rates increase ancillary wage costs, because employers must pay for 50 per cent of each worker's health insurance contribution. Higher ancillary wage costs increase the price of labor and thus threaten employment in Germany.

In addition to the stabilization of contribution rates, all important reform measures since the 1980s have had the following objectives:

- enhancing competition to increase the efficiency of resource allocation in the hospital sector,
- increasing efficiency in each hospital.
However, one constant has remained in Germany's system of hospital finance: the concept of "dual" finance.

The Health Care Reform Act (GRG) of 1989 was the first step towards global health care reform taken by the conservative-liberal government under Helmut Kohl. The GRG had only minor effects on the hospital sector, which had already undergone a separate reform in 1984 with the Hospital Reform Law (KHNG).

Since implementation of the KHNG, hospitals have had so-called "flexible" budgets. Under flexible budgets, hospitals are not reimbursed for all operating costs: According to the original provisions of the KHNG, if a hospital exceeded the amount specified in its annual budget, the excess amount was covered at a rate of only 25 per cent. In other words, it was assumed that fixed costs make up 75 per cent of a hospital's operating budget and that these fixed costs are covered by the annual budget.

The second stage of the Kohl administration's reform plans went into effect on January 1, 1993 with the Health Care Structure Act (GSG). This law represented a fundamental change within the dual system of hospital finance. It linked the growth of the total budget for the hospital sector in the years 1993 to 1997 to the increase in the revenues of the SHI system. The principle of "fixed" budgets replaced the principle of "flexible" budgets for a transition period. Over the medium term, the GSG replaced the principle of full cost coverage by a system based on prospective and service-oriented fees. More detailed regulations were laid down in the Hospital Rate Ordinance of 1995 (BPflV 95), which stipulated that a greater share of hospital services are to be covered by lump-sum payments per case and procedural rates instead of by per diem rates.

The GSG also granted hospitals the opportunity to provide a limited amount of ambulatory services to hospital patients prior to and immediately following their hospital stay. Furthermore, hospitals were allowed to provide day-case surgery. By expanding hospitals' rights to provide outpatient care, the law placed hospitals in direct competition with doctors in the office-based sector.

The third stage of the health reform began in 1997 with the implementation of the First and Second Laws for the Reform of the SHI System (1. and 2. GKV-NOG). The law transferred responsibility for the maintenance and development of the hospital reimbursement system to representatives of the hospitals and the SHI funds. In addition, the strict budgets in the hospital sector were adjusted to reflect medical need and medical progress.

Following the election of the present administration under Chancellor Gerhard Schröder, the Law for Reinforcing Solidarity in the SHI System (GKV SolG) went into effect on January 1,
1999. The law was seen as the first step towards a comprehensive reform of the health care system that was planned for the year 2000. The GKV SolG removed all measures of the previous government that increased patient cost sharing in the SHI system and re-introduced strict budget limits for each hospital in 1999.

3.1.2.1 Reimbursement of hospital services

The current system for the remuneration of hospital services is based on the Hospital Rate Ordinance (BPflV 95), which has been in force since 1995/96. It is likely that this system will remain in effect until introduction of the new remuneration system that is planned for 2003. In the context of the "dual" system of hospital finance, the Hospital Rate Ordinance is related only to the operating costs and not the capital costs of acute care hospitals.

The current system for the remuneration of hospital services in Germany is a hybrid that combines per diem payments with lump-sum prospective rates. These are also the basic units that are used for the calculation and negotiation of each hospital's budget. The budget of a hospital is determined each year in negotiations between health insurance funds and each hospital. The base line for the negotiations is the hospital's budget from the previous year. In addition, planned changes in the structure and volume of services or expected changes in hospital revenues are taken into account.

Strictly speaking, the budget agreed upon in the negotiations is fixed only if the hospital actually provides the type and volume of services that are specified in the budget. Deviations of a hospital's actual proceeds from its budget are partially compensated through budget adjustments ("flexible" budgeting). Such adjustment reflects only variable costs. Hospital services in excess of the agreed upon volume and structure are paid for at only 10 to 15 per cent of the normal rate. If a hospital provides fewer services than specified in the budget, the difference between the negotiated budget and actual services provided is covered only to 40 percent. These regulations make it unattractive for hospitals to provide more or less than is specified in their annual budgets.
In addition to the level of a hospital's budget, the scheduling of payments to the hospital over the budget period is subject to negotiation. The basic per diem for all non-medical services (e.g. administration, accommodation, meals) is negotiated separately. The basic per diem is paid to a hospital for each day of in-patient stay and is the same for all departments in a hospital.

Each department in the hospital is also paid a separate "departmental" per diem (Abteilungspflegesatz) for each day of patient stay in the respective department. The per diem rates (the departmental per diems and the basic per diem) are determined in annual budget negotiations and are based on the expected type and volume of the each department's services.

The per diem rates must be medically justified and enable a prudent hospital administration to meet the contractual obligations of the hospital in the provision of health care. Hospitals are not entitled to have their costs reflected in the negotiated budgets. However, a hospital is entitled to a negotiated budget that reflects differences in the type and volume of its services vis-à-vis other hospitals.
The Hospital Rate Ordinance (BPfL V) defines lump-sum payments (Fallpauschalen) and procedural rates (Sonderentgelte) for certain types of treatment. The procedures and services covered by these forms of payment may not be paid on the basis of per diems. The relative values of the per-case payments and procedural rates are determined at national level and are based on an empirical study of the average costs in selected hospitals.

The value of the lump-sum-payments and procedural rates in monetary terms is negotiated each year at state level. The amount of payment for a given type of treatment is therefore the same for all hospitals within a state.

Per-case payments are defined according to diagnosis and cover all medical and non-medical hospital services associated with the care of a patient. If a lump-sum per-case payment exists for a diagnosis, other forms of payment cannot be used for billing purposes. Only when the length of inpatient stay exceeds the maximum length of stay that is defined for each per-case payment is a case regarded as an "outlier". Inpatient days in excess of the maximum length of stay are paid for on the basis of per diem rates (i.e. basic and departmental per diems).

Procedural rates are designed to cover the costs of specific procedures, including the costs of implants and transplants as well as laboratory and surgical services that are utilized during a procedure. The remaining costs related to the hospital stay are paid with per diem rates. Non-medical services of the hospital are covered by the basic per diem, which is paid in full. In order to avoid a "double counting" of the costs associated with medical treatment, which are also covered by the departmental per diem, only 80 per cent of the departmental per diem is paid to the hospital.

On average, per diem rates cover about 75 - 80 per cent of hospitals' budgets for inpatient care. However, this rate varies widely across hospitals. Lump-sum payments and procedural rates are very important for the remuneration in some medical specialties, in particular in heart surgery, transplantation medicine and in orthopedic surgery. Thus, prospective hospital rates make up much more than 20 to 25 per cent of the budget in hospitals that are specialized in these areas.

All operating costs of a hospital during a budget period are charged to individual patients or their health insurers on the basis of per diem rates, lump sum payments and procedural rates. The payments therefore do not function as prices for hospital services, but as installments towards payment of the negotiated hospital budget.

The present reimbursement system fulfills its function of financing the services provided by hospitals. In addition to the finance function, a rational reimbursement system must also fulfill the function of allocating resources. This includes ensuring that scarce resources are allocated to
the more efficient health care providers. However, due to the state subsidization of hospitals' capital costs (system of the dual finance) and the characteristics of the current reimbursement system, the present system of hospital finance is much less successful in fulfilling the allocation function than it is in fulfilling the finance function.

In addition to inpatient treatment, hospitals can provide "pre- and post-stationary" services, semi-stationary and short-term inpatient treatment as well as ambulatory surgery. Special per diem rates for semi-stationary services are determined in the annual budget negotiations. The other forms for the provision of hospital services are usually reimbursed on the basis of lump sum payments. The following figure provides an overview of the different types of hospital rates.

Overall, the most hospital revenues stem from services provided on a "full" inpatient basis. The revenues from other types of services are marginal. The following discussion of the hospital sector therefore focuses on services that are provided on a "full" inpatient basis.
3.1.2.2 Finance of capital costs

The aim of the Hospital Finance Act (KHG) is to provide a sound financial basis for hospitals and thus maintain an adequate supply of hospital facilities. The implementation of the KHG is the responsibility of the states. Each state determines the volume and structure of the hospital supply and finances the capital costs of hospitals to meet the demand of the population. However, although state governments fund their capital costs, hospitals are independent economic units.

Hospital supply is determined in hospital plans that are drawn up at state level. Thus, there are 16 different hospital plans in Germany, which are largely similar with respect to structure and methodology. The responsible state authorities update these hospital plans periodically. The admission of a hospital to the respective hospital plan of the state in which it is located is a prerequisite for the public funding of capital costs.

Inclusion in a hospital plan also entitles a hospital to a "supply contract" (Versorgungsvertrag) for the treatment of patients insured under the SHI system. The SHI funds are obliged to pay for those hospital services that are provided to their insured under the terms of this contract. This is of vital importance to hospitals since approximately 80% of a hospital's revenue is covered through such "supply contracts".

The separation of the planning and finance of hospital supply is one of the main points of criticism of the system of dual hospital finance. Critics argue that it would be more appropriate to give health insurance funds - as the main financiers of the hospital sector - at least a stronger voice in the hospital planning process or to abolish hospitals' entitlement to a "supply contract".

The regulations and procedures for the finance hospitals' capital costs are specified in the Hospital Finance Act (KHG). The law distinguishes between funding that must be applied for, lump-sum support and the funding of maintenance measures. The following figure provides an overview of the different types of funding of capital costs in the hospital sector.
Under the current system of hospital finance, hospitals that are in a state's hospital plan can receive funding for hospital construction (new buildings, renovation, expansion), including the costs of setting up a hospital (technical equipment and furnishings), by applying to the responsible state authority. In order to receive such funding, hospitals must submit utilization plans and provide evidence that the capital expenditures are "economical". Hospitals may use the same procedure to apply for funding for capital goods with an average service life of more than three years.

States also finance the replacement of capital goods with an average service life of less than three years as well as small construction measures. This funding does not occur upon request of the hospital, but via fixed annual lump-sum support. This financial support is earmarked, although hospitals can use them freely.

The level of lump-sum support for a hospital is related to the level of care provided by the hospital and - to a great extent - by the number of beds in the hospital. The level of lump-sum support varies widely across the states. In 1998, the average amount of lump-sum support per
bed or treatment unit was DM 3,953. The lowest level of support was in Saxony (DM 2,655) and the highest in Bremen (DM 5,065).

Since 1997, in accordance with the "Second Law for the Reform of the Social Health Insurance System" (2. GKV-NOG), the costs of maintaining hospital facilities are no longer paid by state governments but by the health insurance funds. These costs are covered through a 1.1 per cent markup on the budget of the each hospital.

In practice, it is not always easy to distinguish between capital goods and non-durable goods that are used in medical treatment. From a management perspective, the present system of hospital finance has the disadvantage that decisions concerning hospital capacity, the range of hospital services thus the cost factors in the hospital are removed from the hospital and shifted to government authorities. State control of capital spending limits hospital autonomy and tends to limit competition.

Moreover, in times of empty public treasuries, it is likely that state governments will provide hospitals with less funding, so that important capital projects cannot be undertaken or are delayed. In the medium-term, this endangers the standard of the medical care in the hospital sector. At present, most state governments in Germany do not provide sufficient financial means for the capital spending needs of hospitals. The gross investment ratio in the hospital sector is presently about 7 per cent of hospital revenues. However, the actual capital needs of the hospital sector are more likely in the range of 15 per cent of revenues.

Due to the scarcity of funding and the prolonged procedure for the awarding of funding, many hospitals - in particular those in private ownership - are turning increasingly to private capital markets to circumvent the cumbersome and inefficient public funding system. Despite the loss of funding by the public purse, these hospitals profit from the competitive advantages that result from the increase in decision-making freedom and greater flexibility with respect to the timing of decisions.

### 3.1.2.3 Special status of university hospitals

Germany's 35 university hospitals have a special status in the hospital sector. The university hospitals have a total of approximately 50,000 beds, and house most beds that are classified as maximum care beds. On average, the patients treated in university hospitals are more seriously ill than patients in other hospitals and thus require cost-intensive forms of care. In 1995, Germany spent about DM 22 billion on university medicine.
In addition to providing health care to patients, university hospitals provide research and medical training to healthcare professionals. Based on this broader range of possibilities, university hospitals have more funding sources than other types of hospitals:

- The regulations of the Hospital Finance Act (KHG) are not applicable for the funding of university hospitals' capital costs. According to the University Funding Law (HBFG), national government and state governments finance the capital costs of university clinics on a 50-50 basis.

- As in the hospital sector as a whole, health insurers pay the operating costs of university hospitals. The university hospitals are also subject to the general rules of the Hospital Rate Ordinance (BPfL).

- State governments finance the personnel and material costs of medical research and training. In general, this funding is based on a general subsidy (of material costs) to the university clinic and direct financing of the salaries of the clinical and non-clinical research and teaching staff.

- Finally, research projects are being financed increasingly through other sources such as government authorities, the industry, and private foundations.

Based on the combination of research, teaching and patient care, university hospitals play a special role in the clinical trials of new procedures and thus in the market introduction of innovative medical devices. Their role in the innovation process is depicted in the following figure:
After the development phase of an innovative medical device, university hospitals are usually the only facilities with the necessary personnel, technical and financial prerequisites for the performance of clinical trials on a large number of patients. Due to their role as "maximum care" hospitals and their research and training responsibilities, university hospitals have the necessary medical know-how and experience at their disposal. The size, reputation, and service range ensure an adequate number of patients for clinical trials with highly specialized medical procedures. These facilities provide the basis for the broad introduction of new medical devices into the market.

Germany's university hospitals fulfill an important function for innovative manufacturers of medical devices. Due to their role in the provision of training continuing education to medical professionals, they also play a key role in shaping the experience and practice of future generations of doctors. This fact is important for the diffusion of medical technologies in the rest of the hospital sector as well as in the office-based sector after the innovation phase. University hospitals' role with respect to the successful introduction of new medical devices will increase.
when the new mechanisms for the control of medical procedures and medical technology are fully in effect.

### 3.1.2.4 Medical devices in hospital finance

Medical devices must be classified in order to determine their source of finance in Germany's system of "dual" hospital finance. Extensive regulations on the accounting practices for this purpose are contained in the "Ordinance for delimiting capital costs and operating costs" (Verordnung über die Abgrenzung der im Pflegesatz nicht zu berücksichtigenden Investitionskosten von den pflegesatzfähigen Kosten der Krankenhäusern - AbgrV). The following figure shows the fundamentals of these regulations:

![Diagram of Medical Devices in the System of Dual Hospital Finance](source)

The ordinance makes a basic distinction between medical devices as capital goods (e.g. large medical equipment) and medical devices as consumption goods (e.g. implants, dressing material). Capital goods are classified as the fixed assets of a hospital. If they are purchased for the construction and initial fitting of a hospital, the finance of medical devices that are classified as capital goods occurs on the basis of an application to the responsible state authorities. The
finance of medical devices that are capital goods but not purchased during the original construction depends on the average service life of the device. Medical devices with an average service life of more than three years are also financed on the basis of tax-funded state grants.

Medical devices with an average service life of less than three years are classified as current assets and considered "consumption goods". Depending on their purchase price, the costs of consumption goods are financed through per diem rates, per case payments, procedural rates or lump-sum support.

Medical devices that do not enter hospitals' balance sheets as fixed assets are used primarily in the provision of care. These devices are financed completely on the basis of per diem rates, per-case payments and procedural rates. The forms of the remuneration for hospital services have different effects on the utilization of medical devices in the provision of health care services.

With per diem payments, all medical devices that find "final use" in the course of medical care are paid on the basis of a hospital's basic and departmental per diems. The price for the provision of treatment to any given patient does not reflect the actual costs of the services provided to the patient but is the result of annual budget negotiations. In effect, hospitals are paid the average daily cost of treatment of the forecasted number of patients. The effects of the utilization of a medical device on hospital revenues therefore differ according to hospital.

The situation is different when hospital services are paid on the basis of per-case payments or procedural rates. These fees are based on an empirical estimate of the average costs of different hospitals.

Separate estimates were made for personnel costs and material costs. The material costs include the costs of medical devices. The ratio of the cost elements is preserved by the procedure for adjusting per case payments and procedural rates to general price increases.

However, innovative medical devices typically change the original ratio of personnel to material costs. An increase in material costs due to the increased use of medical devices is often offset by a decrease in personnel costs due to a shorter length of stay. Since this can result in an increase in the total costs of hospital treatment, the re-calculation of per case payments and procedural rates is necessary on a regular basis. In the long run this is the only means for ensuring that medical-technical progress is not withheld from the patients because of inadequate reimbursement.

### 3.1.3 The need for reform

The system of the "dual" finance is a special feature of the German hospital sector. For years it has been subject to criticism that focuses on three points:
• the mixture of per-case payment and per diem rates for the remuneration of hospital services.

In general, most hospital services are paid for on the basis of per diems. This reduces hospitals' incentive to reduce the length of hospital stay.

• Hospital finance is still based largely on the concept of cost reimbursement.

There is no clear connection between the provision of services and payment. Hospitals thus have few incentives to improve efficiency. Furthermore, the available financial means are not allocated efficiently in the hospital sector. As a result of this waste, the hospital sector cannot treat the maximum number of patients possible.

• The separation of capital and operating costs.

Decentralized investment decisions have been shown to be superior to centrally planned decisions in almost all sectors of the economy. There is no reason why the hospital sector should be an exception to this rule.

These points of criticism have been taken up in a number of reform initiatives. The fear of major changes has blocked all significant reforms over the past 10 years.

3.1.4 Central aspects of the “Health Care Reform 2000”

The German government introduced a revised version of legislation for the "Health Care Reform 2000" in November 1999 that was purged of all measures that would require the consent of the Bundesrat (Upper House of Parliament). The new version of the law no longer contained two central points of the original draft legislation: the introduction of a global budget and the transition to single source hospital finance. The remaining reform measures for the hospital sector are:

• the introduction of a case-based remuneration system for hospital services.

• the introduction of a technology assessment committee to evaluate the cost and efficiency of medical technology and the strengthening of the role of clinical guidelines.

• the linking and networking of hospitals with office based physicians

After months of political and public debate, the remaining measures were somewhat different than those contained in the original draft, but the modifications were not significant.
Instead of a global budget, strict budgeting by sector will be kept in place. Measures for statewide limits on total spending, single-source hospital finance and selective contacting were deleted completely.

The Bundestag passed the new draft on 16.12.1999. The reform legislation went into effect on 01.01.2000 as originally planned.

3.1.5 Reorganization of the hospital sector

3.1.5.1 Hospital budgeting until 2003

A central item of the health reform 2000 for the hospital sector is the introduction of a universal prospective payment system for hospitals beginning in the year 2003. Until implementation of the prospective payment system, provisional measures will apply.

The "global budget" approach, which would have placed a limit on healthcare expenditures as a whole, was replaced by single budgets for each sector. For the hospital sector, this does not represent a substantial change. However, the new law links spending developments in the hospital sector more rigidly to revenue trends of the SHI system. The aim of this measure is to maintain the stability of contribution rates in the SHI system.

The Health Care Reform 2000 extends the limit on spending in the hospital sector - a measure that was introduced under an interim law at the beginning of 1999 - to the year 2003. Annual budget negotiations will continue to take place between each hospital and the health insurance funds. However, the basis for budget agreements is the budget of the previous year, adjusted to reflect changes in the revenue base of the SHI system.

The budget of a hospital may exceed this rate only in exceptional cases. The exceptions include changes in the service structure of a hospital and fluctuations in the number of patients treated in a hospital. The exceptions no longer include the annual wage increases of hospital staff.

Under these essentially fixed budgets, hospitals will be able to improve their earning situation by cutting costs. However, the budget regulations do not reflect the effects of medical progress, which together with the aging of the population and the increase in polypathic patients will accelerate the increase in treatment costs. Thus, the budget regulations in the hospital sector should result in a rationing of hospital services if the forecasted cost increases are not offset by hospitals. In this case, it will be necessary to create "waiting lists" for elective surgery and could even threaten the existence of some hospitals.
Spending limits on the hospital sector will increase the need for increase efficiency in hospitals. This will promote the use of medical devices that help reduce the length of stay. However, over time, the range and structure of a hospital's services are no longer reflected by the budget, which could have negative effects on the quality of care. Under certain conditions, less expensive procedures may be used instead of the most modern and least invasive procedures. Such developments could pose a threat to maintaining the high quality of health care in Germany.

3.1.5.2 Introduction of a per-case reimbursement based on Diagnosis Related Groups

If all goes according to the lawmakers' plan, a "service-based" method of budget calculation will replace the procedure of updating each hospital's budget in annual budget negotiations beginning in the year 2004. Towards this end, a comprehensive, service-based prospective payment system will be introduced for all hospital services (inpatient and semi-stationary), including university hospitals, in 2003. The sole exception to these regulations is psychiatric facilities.

The law contains a fairly specific description of the basic elements of the new hospital reimbursement system: The system must be able to accommodate complex cases and patients with co-morbidity yet remain manageable enough for actual use. The (relative) level of the individual lump-sum payments is to be determined using relative values (cost weights) and a standard service (basic rate). The law states explicitly that the new reimbursement system is to be based on Diagnosis Related Groups (DRG system). The self-management authorities in the SHI system are responsible for determining the details of the reimbursement system.

In addition to the general requirements for the new reimbursement system, the law also specifies a binding schedule for the implementation of the system. The deadlines are not as tight as in the original draft legislation. Nevertheless, given the experience in other countries, the schedule is very ambitious. It is therefore questionable whether the deadlines can be met. The following figure gives an overview of the schedule and deadlines.
This schedule, which was drawn up by the German government distinguishes four steps:

Step 1: Basic Decisions

By June 30, 2000 the self-management authorities must agree on:

- the basic structure of the hospital reimbursement system.

The national associations of SHI funds, the association of private health insurers and the German Hospital Federation must focus thereby on "an remuneration system based on Diagnosis Related Groups (DRG) that has already been implemented in another country".

Such systems are applied at present in the USA, in Australia, Norway, Portugal and France. However, these do not represent a single DRG system; each is a special national system. All are based to a greater or lesser extent on the so-called HCFA DRG system used by the Health Care Financing Administration (HCFA) in the USA or on the AP-DRG system (the All Patient Diagnosis Related Groups) used in New York State.

The self-management authority also has until June 30, 2000 to reach an agreement on:
• The classification system, which groups patients (cases) according to the amount of treatment they receive. Comparable remuneration systems contain more than 500 categories.

• The national procedure for the calculation of the cost weights for each group. The cost weights reflect differences in the treatment expenditures of each group.

• The fundamentals of the procedure for the adjustment of the reimbursement system to the medical and technical developments as well as cost trends. The law specifies that the adjustment method is to be based on a procedure that is already used in another country.

• The definition of special services that justify nationally uniform surcharges or markdowns for individual hospitals. Special services are such services that are not provided by all hospitals, such as emergency care or the provision of unprofitable hospital facilities in rural areas.

If an agreement is not reached on these points by the date specified, the national government will issue a decree.

With respect to the provision of appropriate care using modern, innovative medical technologies, the definition of the patient categories, the calculation of cost weights for each category, and the procedure for the adjustment of the remuneration system over time are of central importance.

An operational prospective payment system must be designed to ensure rapid adjustment to new procedures. Patients' access to modern medical procedures in the hospital sector can only be ensured when the reimbursement of the procedures are determined without delay.

**Step 2: Valuation**

Based on the agreement that is to be met by June 30, 2000, the self-management authorities have until December 31, 2001

• to calculate the cost weights for each patient category and

• to determine the level surcharges and markdowns.

The assessment of the cost weights "may be calculated on the basis of a sample of hospitals, be taken from a system that has already been deployed in another country or be based on a foreign system". The cost weights reflect the amount of services needed for the care of a given case group in relation to the average amount of services. In the logic of a DRG-system, multiplying
the cost weights of a case group by the average value per case results in the level of the prospective payment.

Given the short time period of 18 months between the end of June 2000 and the end of December 2001, it seems highly unlikely that a careful calculation of cost weights can be made to reflect the specific conditions in the German hospital sector. The direct application of cost weights from a DRG system in another country could lead to results that differ considerably from current reimbursement rates. There are already indications that this is the case for heart surgery and cardiology. It is likely that inappropriate cost weights will have negative effects on the use of innovative medical devices. In order to ensure that patients receive the care they need, the cost relations in all medical areas must be calculated.

The law designates that the level of the prospective lump-sum rates may differ according to region, as is the case in the current system of per case payments and procedural rates (Fallpauschalen and Sonderentgelte). Hospitals in the same region will receive the same level of payment for the provision of care to patients in a given category. In general, the level of payment will be independent of the cost structure in each hospital. Differences between hospital rates can result only from the surcharges and markdowns that are agreed upon at national level.

Step 3: Preparation

Following determination of the cost weights and the level of surcharges and markdowns, hospitals and health insurers have exactly one year to make administrative preparations. It is likely that staff training and the conversion of data processing will pose the greatest problems. The new prospective payment system will go into effect on January 1, 2003; and will be "budget neutral" during the first year of use. More detailed regulations on the implementation of the new system must be determined in "Hospital Fee Ordinance" (Krankenhausentgeltordnung) that will replace the existing "Hospital Rate Ordinance" (Bundespflegesatzverordnung) at the start of 2003.

Each hospital's budget for the year 2003 will be agreed upon - as in the previous years - on the basis of the budget review conducted in the annual budget negotiations and independently of the remuneration system. The new remuneration system will be used during the first year only as a means for determining the health insurers' "installments" towards payment of each hospital's budget. Thus, the only change for hospitals in the first year is the accounting procedure. The existing system of per-case payments, procedural rates and per diems will be replaced by the new prospective payment system. Individual hospitals will suffer no financial loss. The remuneration system serves merely as an instrument for budget allocation in each hospital.
Step 4: Implementation

Beginning in 2004 the new remuneration will be used as a tool for determining a hospital's budget on the basis of the services it provides. This can occur prospectively on the basis of a forecast of the hospitals expected services. In a second step, hospitals can use the new reimbursement system to calculate the installments of health insurers for the payment of the hospital services that are provided. Regulations for adjusting payments in cases in which the expected volume of services is not realized during the budget period are to be determined in the Hospital Fee Ordinance.

Under a DRG-system, it will be possible to allocate the total budget for the hospital sector to each hospital on the basis of the services provided by each hospital. However, there will be winners and losers among the hospitals in comparison to the present situation. In general, the new reimbursement system will tend to increase trends towards concentration and restructuring in the hospital sector. In order to offset negative social effects, an interim mechanism to compensate shifts within the hospital sector is needed.

The prospective payment system will provide hospitals with clear indicators for economically rational behavior. Experience from other countries shows that a clearly defined prospective payment system increases efficiency in the provision of health care. In general, this will tend to increase the opportunities for the utilization of innovative medical devices, and especially of those devices that can shorten the length of stay.

If a lump-sum payment is not enough to cover a hospital's costs in the provision of a service, then this service should be performed by hospitals that can provide the service at less cost. This will make it possible to treat more patients without increasing resource use, and the overall efficiency of the hospital sector will improve.

Whether the reform measures will have the anticipated effects will be revealed after 2003. If the effects do not come to fruition, lawmakers will soon undertake a further reform. It should not be forgotten that the next national elections are scheduled for the fall of 2002. It is therefore possible that a new government would once again modify the political approach and modify the introduction of the new system for the remuneration of hospital services.

3.1.6 Hospitals in a dynamic environment

Social and demographic change in Germany will have a profound effect on the hospital sector. The full effects of these changes - on the need for hospital care and on the demand for and supply of hospital facilities - are still evolving. Demographic effects will be intensified by
continued medical progress. Some important trends in the hospital sector are already evident today.

3.1.6.1 The demand side

The need for health care services will continue to rise over the next decades. The main factors behind the increasing need for hospital care:

- the expected demographic development due to increasing life expectancy and
- rapid medical progress.

The demographic development of the Federal Republic of Germany has been characterized for decades by the aging of the population. As a consequence, the proportion of hospital patients over 60 years of age has increased during the past 15 years by more than 13 percentage points. The following figure shows that this rate of increase is clearly larger than the increase of this age group in the total population.
This demographic trend is likely to continue far into the 21st Century. The health care needs of the elderly and very elderly will continue to rise. As a patient group, the elderly will become even more important for hospitals in the future.

As a result of this trend, the range of diseases treated in the hospital sector will change over time. Hospitals will have to focus more on the treatment of chronic-degenerative diseases and patients with more than one disease. Resource utilization in the hospital sector will grow.

The increase in the number of elderly hospital patients cannot be explained by demographic trends alone. The forecasted increase in demand is closely related to rapid development of new medical procedures, which are utilized more intensely by the elderly. That is demonstrated in the following figure, which provides an overview of heart surgery in Germany:

Between 1992 and 1998 the number of heart surgeries performed in Germany increased two-fold from approx. 49,000 per year to approx. 97,000 per year. At the same time the number of procedures performed on patients over 80 years of age increased almost five-fold. This example
reveals how medical and technological progress has increased the possibilities for performing complex surgeries on elderly patients.

Medical progress does not only benefit the elderly. There are also new means for treating younger persons with diseases or injuries that were once fatal despite intensive hospital care. New and improved methods of diagnosis and treatment are generally inseparable from the use of the cutting-edge technologies in hospitals.

Trends in the need for hospital care will have a profound effect on future market opportunities for innovative medical devices. Changes in the subjective perception of the need for health care will reinforce this trend. Greater individual expectations with respect to the health care system will play an increasing role in the marketing of innovative medical devices. Since patients are often willing to pay more to receive "optimal" care, hospitals must accommodate the changing expectations in order to compete successfully with other hospitals. The utilization of the results of medical research and development is therefore in hospitals' own interests.

Health Insurance Funds as Customer

The need for health care can only lead to the utilization of these services if it results in demand with sufficient buying power. The utilization of health care services in Germany is financed primarily by the social health insurance funds. These can therefore be regarded as the "customer" of hospital services.

There have been sweeping changes in the demand for hospital services since 1991. Even before the discussion of re-organization of the SHI system and the introduction of open enrolment regulations (1996/97), there was a marked concentration process in the SHI system. Those types of SHI funds that were threatened more than others by competitive processes, the "general local SHI funds" (Allgemeine Ortskrankenkassen - AOK) and the "guild health insurance funds" (Innungskrankenkassen - IKK) merged at an unexpectedly rapid rate. In comparison, there were almost no mergers among the substitute health insurance funds (Ersatzkassen) and even less among the company based health insurance funds (Betriebskrankenkassen - BKK). The decrease in the number of SHI funds from 1,235 to 467 over the 8-year period 1991 to 1999 is shown in the following figure.
This restructuring of the SHI funds was urgently necessary since the introduction of open enrolment regulations provided a basis for the migration of the insured within the whole SHI system.
The above figure shows that the main losers of the open enrolment regulations were the local SHI funds (AOKs). Since 1996, the AOKs lost almost 1.8 million members. These individuals moved mostly to the company-based funds (BKK) and the substitute funds (EAN). However, the trend shifted for the EAN in 1997. Up to 1997 the number of people covered by the EAN funds increased. Since then this number has also declined. An important reason for the change in insurance fund is in the majority of cases the differences in contribution rates.

There was not only a migration between the types of SHI funds but also within each type of SHI fund. The loss of members varies markedly among the AOK funds and the same applies to the substitute funds. Although the large substitute funds like the "Barmer Ersatzkasse" (BEK) and the "Deutsche Angestelltenkrankenkasse" (DAK) lost members, the number of persons insured by the Techniker-Krankenkasse (TK) increased.

A drop in membership is particularly problematic for SHI funds, since it is usually younger members that change funds; i.e. members that cause less expenditures yet pay relatively high contributions. The SHI funds with dramatic losses in membership are therefore coming under
increasing pressure. This pressure is passed on to the hospitals, which represent the largest share of the SHI funds' expenditures.

In view of the increased migration of SHI members and the economic processes to which this trend gives rise, it is likely that the concentration process among the SHI funds has not yet reached its conclusion. The concentration among the SHI funds will tend to strengthen the negotiating position of the SHI funds in the annual negotiation of hospital budgets and result in more professionalism in the negotiation procedures. Large insurance funds will call increasingly for the right to negotiate alone with individual hospitals. This would be the first step towards selective contracting in Germany's SHI system.

SHI funds with a solid financial basis will try to assert themselves in the health insurance market as innovative funds that offer their members high-quality health care. Medical device manufacturers can utilize such strategies of the SHI funds to leverage the introduction and utilization of their products.

3.1.6.2 The supply side

A profound restructuring can also be observed in the hospital sector itself. This process does not appear to be finished yet; in fact, they seem to be occurring at an accelerated rate. The changes within the hospital sector are particularly evident in

- a growing number of proprietary hospitals,
- a decrease in the number of small hospitals,
- a rapid increase in the market shares of large proprietary hospital chains.

These three trends will also have indirect effects on the medical device industry as the suppliers of hospitals.

The restructuring in hospital ownership has weakened the position of hospitals in public ownership. The number of public hospitals decreased by about 18 per cent between 1991 and 1997, while the number of the voluntary hospitals remained more or less constant. In contrast to these two groups, the number of proprietary hospitals increased over the same period by 52 hospitals or 16 per cent (see figure below).
The above figure also reveals the decrease in the number of small hospitals with a capacity of less than 200 beds. Between 1991 and 1997 more than 60 hospitals in this group were closed. These hospitals were predominantly in public ownership. This trend is a reflection of the increasing difficulties of smaller public hospitals to hold their ground in times of chronically scarce public funding. The increase in the number of proprietary hospitals has expanded the market position of privately owned hospitals, in particular those with more than 200 beds.

What the above figure does not reveal is that some of the public and voluntary hospitals that are classified as closed have actually been transferred into private ownership.

In summary, the reorganization of Germany's hospital sector can be characterized as follows:

- the number of proprietary hospitals is rising, in particular the number of large proprietary hospitals;
- the decreased in the number of hospitals and beds in public ownership is due largely to the downsizing and closure of small hospitals;
while the number and bed capacity of voluntary hospitals have decreased, they have not declined as markedly as in the public sector.

The winners of this restructuring process, the private hospitals, often belong to large hospital chains. Such hospitals networks have a stronger negotiating position vis-à-vis suppliers because of central purchase agreements. From the perspective of the medical device industry, hospital chains are important customers that can influence the selling prices of medical devices. Private hospital chains can have competitive advantages over public or voluntary hospitals that result not only from better procurement conditions but also from their different management structure.

The competitive advantage of proprietary hospital chains is evident in the rapid increase in the number of patients treated. The number of the cases treated by the three largest hospital chains grew more than fivefold between 1990 and 1997, while the number of cases treated in all hospitals increased only moderately. This shift in market shares to the large private hospital chains is illustrated in the following figure:
The strong growth trend in the market shares of proprietary hospital chains is likely to continue in the future. Thus, there will be increasing pressure on the prices of medical devices that are used in hospitals and on the profit margins of the medical device industry.

Proprietary hospitals - and in particular hospital chains - often compete for patients by offering advanced medical technology. The more frequent utilization of the most modern medical devices, which usually have higher procurement costs than older technologies, will increase the share of material costs in total treatment costs. The following figure shows that the share of material costs in hospital costs is higher in proprietary hospitals than in public hospitals in both the USA and Germany.

The higher share of material costs in proprietary hospital chains (Rhoen hospitals AG and Columbia / HCA), is due largely to a higher degree of outsourcing in private hospitals. The higher share of material costs in the proprietary hospital chains also reflects the greater expenditures for the procurement of medical devices.

The application of innovative medical devices contributes in many cases to a reduction in the length of stay. The increased utilization of medical devices that are instrumental in reducing...
patients' length of stay reduces the need for nursing personnel. In economic terms, this targeted use of medical devices represents the substitution of labor by capital in the provision of health care.

In Germany, the conditions for the substitution of labor with capital are more favorable for proprietary hospitals: In contrast to public and voluntary hospitals, proprietary hospitals are not subject to wage agreements for public sector workers. It is therefore easier for proprietary hospitals to transfer nursing personnel into other areas or reduce staff size.

General trends in the market for hospital services in Germany appear to confirm the private sector's strategy based on the increased utilization of medical devices. This is illustrated by the success of the large private hospital chains that pursue this strategy. In the future, it can be expected that there will be an increasing trend towards the utilization of capital (and thus of medical devices) and of less personnel in the provision of hospital services in Germany.

3.1.7 Medical devices and hospital economics

Under competitive conditions, hospitals must strive to improve its efficiency and thus produce more with the same amount of resources. This allows hospital either to treat more patients with the same amount of resources or to improve treatment outcomes with the same resource application.

The most important option for hospitals caught between the demand for more quantity and quality and scarce funding is the use of new and efficient treatment methods. Innovative medical devices are often the motor for such improvements in efficiency and effectiveness.

A hospital usually invoices health insurance funds directly for the care provided to their members. These revenues are accounted against the costs that arise in the course of hospital care. The ratio of revenues and costs provides information on the efficiency of hospital care from the hospital's perspective. The main question for the hospital is: Can a new procedure lead to either an increase in revenues or a reduction in costs? However, this economical rationale considers neither the positive effects of new procedures on the health care system nor on the national economy.

In the long run, this hospital strategy can only be successful if it doesn't damage the "image" of the hospital in the eyes of potential patients.

An overview of the different combinations of treatment results and changes in the revenue-cost ratio that result from the application of a new procedure is given in the following figure.
From the individual hospital's perspective, a procedure that improves the revenue-cost ratio and treatment results has the best prospects for implementation (+++). The chances for widespread use of such procedures are better than for procedures that increase the revenue-cost ratio but have no effect on the outcome of care (+ +) or for procedures that leave the revenue-cost ratio unchanged but produce better outcomes (+). The market chances for medical devices that are less efficient and lead to poorer outcomes (- - -) are very limited.

The diagonal cells (?) contain procedures for which the individual situation of a hospital is decisive. A hospital with high utilization rates and a budget deficit would tend to use procedures in the cell on the lower right: In this case, the improvement in efficiency is more important than the possible image improvement and the chance to attract more patients. A hospital that does not have enough patients would tend to use procedures that are described by the cell in the upper left hand corner of the matrix: Efficiency improvements are less important than a better utilization of hospital capacity. The middle cell describes the situation in a hospital in which the introduction of a new procedure has neither economic nor medical effects, but can improve hospital growth.

With a given reimbursement system a hospital cannot usually increase revenues from the treatment of a patient through its choice of a procedure. Hospital management therefore concentrates on cost factors.
The following figure shows the average cost structures in the German hospital sector from the year 1997.

**Structure of Costs in the Hospital Sector**

![Pie chart showing cost structures in the hospital sector]

**Total**: 67.8% Personnel Costs  □ 32.2% Non-Personnel Costs □

A characteristic of German hospitals is the high share of personnel costs, which make up more than two thirds of the total costs. A large part (26.8% of the total costs) of the personnel costs is due to nursing costs. It is therefore likely that the greatest savings potential in the hospital are to be found in the area of personnel and in particular in hospital nursing services.

In order to reduce personnel expenditures on nursing services a hospital must reduce the amount of nursing attendance that is necessary in the provision of hospital care. This target is achieved primarily by reducing the hospital length of stay. The application of medical devices that reduce the length of stay thus represents a strategy for lowering of the hospital costs.

However, a hospital's incentive to increase the use of medical devices that reduce the length of stay exists only to the extent that the hospital is actually able to lower its costs. The decisive issue is whether staff reductions are legally possible. Under the present system of hospital
reimbursement, which is based largely on per diems, there is little economic incentive to reduce the length of stay. This situation will change when the planned system of hospital remuneration is introduced.

3.2 The ambulatory sector

3.2.1 The provision of care by office-based doctors

Ambulatory care in Germany is provided by 112,683 doctors (94,907 in the western states and 17,776 in the eastern states). Approximately 72 per cent of the office-based doctors are in solo practice while 28 per cent work in group practices. More than 60 per cent of office-based doctors have a medical specialty (see Figure 3.1).

Figure 3.1 Number of office-based doctors 1990 – 1998
Persons insured under the SHI are provided care by medical doctors as benefits in kind. For socially insured patients, there is no payment at the point of service.

Doctors are paid for their services on a fee-for-service basis, whereby the content of and payment for each service is defined in a national fee schedule. The fee schedule (Einheitlicher Bewertungsmaßstab - EBM) lists some 2,800 medical acts. Each medical act in the EBM has a certain number of points that is supposed to reflect the overhead costs of maintaining a medical practice, the costs of certain single-use items and certain medical equipment costs, the costs of materials used in lab tests performed in the practice and most postage and transport costs.

The billing of the doctors' services is the task of 23 regional associations (kassenärztliche Vereinigungen), which are also responsible for the relationships between doctors and the SHI funds. Other tasks of the regional associations of doctors include the responsibility for the negotiation of contracts with the SHI funds.

Since 1993 the funding of office-based doctors' services has been subject to budget limits. The annual rate of budget increase is determined by law. The actual payment of doctors' honoraria, i.e. the distribution of the total budget for the office-based sector to each doctor, is one of the most important tasks of the regional associations. The distribution of the total budget to the individual doctors is governed by an "honorarium allocation schedule" (Honorarverteilungsmaßstab) that should ensure that the total budget is evenly distributed over a year and that there are no incentives for doctors to provide an excessive amount of services.

To prevent the provision of excessive services by office-based doctors and at the same time prevent the devaluation of the honorarium for each service, regional associations can implement so-called "standard service volumes" (Regelleistungsvolumen). The value of each service is provided at a fixed-point value up to the level of the "standard service volume". If a doctor provides treatment and/or services in excess of the "standard service volume", the excess services can be reimbursed at a reduced rate. The "standard service volumes" are supposed to be defined separately for each medical specialty and include qualitative factors.

Furthermore, the creation of a calculable basis for the reimbursement of doctors' services using "standard service volumes" is designed to shift certain risks (e.g. changes in morbidity patterns, the costs of innovation and shifts in services from the hospital to ambulatory sector) from doctors to the payers.

However, only one regional contract for the introduction of "standard service volumes" has been agreed on (in Bavaria), and it was repealed at the beginning of 1999 when the "Solidarity Reinforcement Law" went into effect.
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3.2.2 The Einheitliche Bewertungsmaßstab

According to §87 of the German Social Code, Book V, the doctors fee schedule (Einheitlicher Bewertungsmaßstab - EBM) is determined in a blanket agreement between the National Association of Office-Based Doctors (Kassenärztliche Bundesvereinigung) and the national associations of the SHI funds. The EBM defines the doctors' services that are covered by the SHI funds and each service's relative value, which is set as a number of points. The catalogue contains over 2,000 codes and is supposed to be reviewed on a regular basis with respect to the definitions of services and the valuation of each code.

Doctors are paid mostly on a fee-for-service basis. According to the Health Structure Act of 1993, the individual codes listed in the EBM are supposed to be bundled into service groups (Leistungskomplexe) and flat rates defined for each group. However, these provisions of the social code have been implemented only for very few procedures.

The EBM is not only a fee schedule, it also defines the services (methods and procedures) that are covered by the social health insurance funds. Procedures that are not listed in the EBM are not subject to general coverage by the SHI funds.

The valuation of the services listed in the EBM can also include the material costs of medical devices or technologies in addition to the payment of the doctor's services. In contrast to the hospital sector, where capital costs are borne by the government and the operating costs by the health insurance funds, all of the costs in the office-based sector are paid for on the basis of fees.

To calculate the monetary value of a service in the EBM, the number of points assigned to a code is multiplied by a so-called point value. Since introduction of budget regulations in the ambulatory sector, point values have been variable. The monetary value of each service and thus the total payment to each doctor can be determined only at the end of an accounting period by dividing the total budget of a region by the total number of points associated with the services provided in the ambulatory sector of the region. Since the point values are subject to pronounced fluctuation and devaluation, office-based doctors are facing growing financial risks.

3.2.3 The invoicing of material costs in the ambulatory sector

The EBM codes cover a range of material costs, including:

- general practice costs;
- costs associated with the use of instruments and equipment;
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• costs of certain single-use articles such as needles, tubes, tracheal cannula, aspirators, gloves, razors, urinary catheters, scalpels, proctoscopes, intestinal tubes, curets, speculae;

• costs of reagents, substances and materials for laboratory services;

• costs of film material and radionuclides;

• some transport and postage costs.

The following costs are not covered by the EBM:

• costs of pharmaceuticals, medical dressings, instruments and materials that can be used in the treatment of only one patient or which the patient keeps for further use;

• costs of single-use infusion instruments, infusion catheters, infusion needles, biopsy needles;

• some telephone costs.

Doctors are also reimbursed for the costs associated with medical devices on the basis of a "practice supply" agreement (Praxisbedarf), which is determined at regional level, or may file separate invoices for the costs of certain medical devices.

3.2.4 Practice supplies

The term practice supplies denotes products such as pharmaceuticals, medical dressings and similar materials that are utilized in each doctor's practice in the treatment of more than one patient (e.g. a large roll of gauze that is used in the treatment of more than patient).

Each of the 23 regional doctors' associations has negotiated agreements with the SHI funds on the provision and coverage of such practice supplies. In essence, the agreements regulate doctors' claims to the replenishment of used practice supplies. The products that fall under this category – certain pharmaceuticals and medical dressings, materials, objects, instruments and single-use articles – are provided to doctors who order them on a quarterly basis by the SHI funds.

3.2.5 Invoicing of material costs

Doctors may submit separate invoices to cover the costs of materials and devices that are not covered by the EBM codes and are not classified as practice supplies. The modalities for submitting such invoices differ according to region.

There is a growing trend in the use of flat rates for the coverage of the material costs associated with certain procedures. Agreements at regional level define the maximum allowable costs of materials used in ambulatory surgery procedures (e.g. intra-ocular lenses in cataract surgery).
Furthermore, in the area of cardiology, flat rates for the coverage of material costs associated with diagnostic catheterization (DM 355), single vessel angioplasty (DM 2,070) and multi-vessel angioplasty (DM 3,420) were introduced nationwide on April 1, 1999.

3.2.6 The reimbursement of procedures that are not listed in the EBM

Health insurers do not have to cover services involving innovative procedures as well as procedures that are considered unconventional or subject to dispute and are not listed in the EBM. However, unless the National Committee of Doctors and SHI Funds has made a negative decision on the procedure involving the device or material, each SHI may assume all or part of the costs of these procedures.

In such cases, coverage of the procedure generally occurs on the basis of "prior approval". The responsible doctor must submit to the patient's insurance fund a cost estimate and statement describing the medical benefits of the procedure and comparison with the standard procedure. The material costs associated with such procedures are generally covered on the basis of separate invoices. Health insurers have become increasingly restrictive in their approval of such procedures.

Another means of obtaining coverage for such procedures is cost reimbursement. In this case, patients enter a private contract with doctors under which the claim to reimbursement is transferred from the patient to the doctor, who then invoices the services provided directly to the patient's health insurer. The patient must pay the difference between the total costs of the service (which are calculated using the Gebührenordnung für Ärzte, the fee schedule for private treatment) and the amount paid by the health insurer.

For those SHI patients whose insurers do not allow for such procedures, these forms of diagnosis and treatment as well as those services listed as "individual health services" (individuelle Gesundheitsleistungen – IGEL) are only available on a self-payment basis.

3.2.7 The reimbursement of medical devices in the office-based sector

3.2.7.1 Medical dressings

The term medical dressings refers to the following products, which are placed on or in the human body to cover wounds, absorb fluids or for the application of pharmaceuticals.
Figure 3.2 Medical dressings

Directly in body cavities to:

a) still bleeding
b) cover, wrap, protect or cushion parts of the body
c) or, in addition to a) and b), contain a pharmaceutical
d) be used instrumentally on the surface of the body to:
   a) still bleeding
   b) absorb wound fluids
   c) cover or protect surface wounds
   d) to cushion and protect injured parts of the body

Indirectly applied externally, with internal action:

a) fixation and correction
b) compression
c) support and relief
d) release of active ingredients

applied externally:

a) to fix articles of A) 2. to the body
b) as a transport medium for pharmacological substances for the treatment of surface injuries

Source: Gerlach, Werner: Kommentierung K§31 Arznei- und Verbandmittel, in: HAUCK / HAINES: Sozialgesetzbuch SGB V, Gesetzliche Krankenversicherung, Kommentar, Erich Schmidt Verlag

Under German social health insurance regulations (SGB V, §35 Abs. 3 Satz 2), the national associations of SHI funds can set reference prices (maximum allowable cost) for medical dressings. Before a decision is made, representatives of medical and pharmacological sciences and practice as well as pharmaceutical manufacturers and representatives of pharmacists are to be given adequate opportunity to voice their expertise. For medical dressings for which no reference prices have been set, the SHI funds cover the costs of the products minus the patient co-payment. Co-payment regulations apply to all SHI patients age 18 and over. If a reference price has been set for a product, the SHI funds cover the price only up to the level of the respective reference price and the patient must pay the rest. Although the German social health insurance regulations allow for the setting of reference prices for medical dressings, they have never been implemented. As a result, patients must pay a co-payment of DM 8 or cover the full price of the product if it is less than this amount.

3.2.7.2 Physical therapy and handicap aids and related products (Heil- und Hilfsmittel)

Due to the difficulty of making a clear distinction between certain types of physical therapy and handicap aids, there is a legal "gray area" for these products. Some material aids are therefore
classified as physical therapy (Heilmittel) while other similar products are classified as handicap aids and related products (Hilfsmittel). Trusses, for example, were formerly classified as "physical therapy", even though they do not have a curative but merely supportive function from a medical perspective.

The need for a precise demarcation grew out of the Healthcare Reform Act of 1989, which introduced reference prices and other changes in co-payment regulations. Under these provisions, there is no co-payment for handicap aids while patients must pay a share of the price of physical therapy. To clarify the distinction between the two groups of products and services, the national associations of SHI funds agreed on the following definitions:

- Handicap aids and related products (Hilfsmittel) are objects (e.g. glasses, hearing aids, orthopedic prostheses, wheelchairs etc.) that either contribute to the success of medical treatment or help patients overcome a physical handicap.

- Physical therapy (Heilmittel) services (in particular services such as speech therapy, physical therapy and occupational therapy) that may only be provided by specially trained and experienced professionals.

Following this definition, some object that certain products that had been classified as "physical therapy" are now classified as handicap aids (e.g. trusses, shoe inlays) and are not subject to co-payment regulations.

The National Committee of Doctors and SHI Funds have incorporated these definitions in its "Guidelines on Handicap Aids and Physical Therapy". Although these guidelines are binding for healthcare providers and SHI funds, it should be noted that the National Committee has no competencies with respect to the determination of legal norms. The definitions therefore only serve to "concretize" norms.

The demarcation problem results from the fact that the social health insurance regulations make only one concrete reference to the definition of "physical therapy" (Heilmittel) in §124 par. 1 SGB V. This passage also allows the conclusion that material forms of "physical therapy" also exist that fall under the National Committee’s definition of handicap aids.

The problem of demarcation is exacerbated by the fact that there is also no clear definition of pharmaceuticals in the social health insurance regulations. The German Drug Act (Arzneimittelgesetz – AMG) and social health insurance regulations have different definitions related to the differing objectives of each law: the AMG is intended to ensure the safety, quality and efficacy of marketed products while the health insurance regulations are intended to define the obligations of SHI funds with respect to the provision of medical treatment to beneficiaries.
The German Health Ministry can "de-list" those forms of physical therapy and handicap aids that it deems to have few or questionable medical benefits or which have a low price. Furthermore, it is possible to remove from coverage by SHI funds those costs that are associated with modifications, maintenance and replacement of products or with the training of patients in their use.

3.2.7.3 Handicap aids and appliances

Under German social health insurance regulations (§128 SGB V), the national associations of the SHI funds are required to compile a "Catalogue of Handicap Aids and Appliances" that lists all products subject to coverage by the SHI system. The catalogue also lists – when applicable - the reference prices or negotiated prices of products as well as the medical and technical quality standards. The term "handicap aids and appliances" encompasses the following products:

- Visual aids (glasses, contact lenses and other aids such as magnifying glasses and electronic magnification equipment),

- Hearing aids

- Prostheses that are used to compensate for handicaps,

- Orthopedic equipment (e.g. orthopedic shoes, orthoses, supports)

- Other handicap aids (e.g. wheelchairs and other mobility aids, appliances for personal hygiene, the performance of daily tasks, reading, speaking etc. and seeing eye dogs)

In order to determine reference prices for these products, they must be classified into groups of similar or related products, a task that is also the responsibility of the national associations of SHI funds. This procedure is meant to ensure that there is a uniform classification of handicap aids and appliances throughout Germany. The classification of handicap aids and appliances is based on a 10-digit code that is structured as shown in Figure 3.3.

**Figure 3.3 The coding of handicap aids and appliances**

<table>
<thead>
<tr>
<th>XX . XX . XX . XX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual product</td>
</tr>
<tr>
<td>Sub-group</td>
</tr>
<tr>
<td>Where the product is applied</td>
</tr>
<tr>
<td>Product group</td>
</tr>
</tbody>
</table>
The following table lists the names of the product groups listed in the National Catalogue of Handicap Aids and Appliances.

**Table 3.1  Product groups in the Catalogue of Handicap Aids and Appliances**

<table>
<thead>
<tr>
<th>No.</th>
<th>Product group</th>
<th>No.</th>
<th>Product group</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Drainage devices</td>
<td>21</td>
<td>Devices for the measurement of bodily functions and/or conditions</td>
</tr>
<tr>
<td>02</td>
<td>Adaptation aids</td>
<td>22</td>
<td>Mobility aids</td>
</tr>
<tr>
<td>03</td>
<td>Application aids</td>
<td>23</td>
<td>Orthoses</td>
</tr>
<tr>
<td>04</td>
<td>Bathing aids</td>
<td>24</td>
<td>Prostheses</td>
</tr>
<tr>
<td>05</td>
<td>Bandages</td>
<td>25</td>
<td>Seeing aids</td>
</tr>
<tr>
<td>06</td>
<td>Radiation devices</td>
<td>26</td>
<td>Sitting aids</td>
</tr>
<tr>
<td>07</td>
<td>Aids for the blind</td>
<td>27</td>
<td>Speaking aids</td>
</tr>
<tr>
<td>08</td>
<td>Insoles</td>
<td>28</td>
<td>Standing aids</td>
</tr>
<tr>
<td>09</td>
<td>Electrostimulation devices</td>
<td>29</td>
<td>Stoma products</td>
</tr>
<tr>
<td>10</td>
<td>Walking aids</td>
<td>30</td>
<td>Braces</td>
</tr>
<tr>
<td>11</td>
<td>Anti-decubitus aids</td>
<td>31</td>
<td>Shoes</td>
</tr>
<tr>
<td>12</td>
<td>Tracheostoma aids</td>
<td>32</td>
<td>Therapeutic exercise equipment</td>
</tr>
<tr>
<td>13</td>
<td>Hearing aids</td>
<td>33</td>
<td>Toilet aids</td>
</tr>
<tr>
<td>14</td>
<td>Inhalation and breathing therapy devices</td>
<td>50</td>
<td>Nursing aids to support the provision of care</td>
</tr>
<tr>
<td>15</td>
<td>Incontinence aids</td>
<td>51</td>
<td>Nursing aids for the provision of hygiene</td>
</tr>
<tr>
<td>16</td>
<td>Communication aids</td>
<td>52</td>
<td>Nursing aids to support independent life style/mobility</td>
</tr>
<tr>
<td>17</td>
<td>Pressure therapy aids</td>
<td>53</td>
<td>Nursing aids to relieve discomfort</td>
</tr>
<tr>
<td>18</td>
<td>Wheelchairs</td>
<td>54</td>
<td>Disposable nursing aids</td>
</tr>
<tr>
<td>19</td>
<td>Nursing aids</td>
<td>99</td>
<td>Diverse</td>
</tr>
<tr>
<td>20</td>
<td>Bedding aids</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Based on this classification, the state associations of SHI funds determine statewide reference prices. These reference prices, which in some cases differ considerably from state to state, are intended to increase price competition within each group and among the providers in different states. Before reference prices are determined, healthcare providers and representatives of the handicapped are to be given an opportunity to voice their opinions on the reference prices.

Once a reference price is set, the SHI funds bear the costs of products only up to their reference price. If a patient chooses a product that is priced above the reference price, he/she must pay the difference.

In the case of vision care products, SHI funds subsidized only a portion of the price of lenses and – since 1997, none of the costs of frames. Patients over 14 years of age are entitled to new vision care products only if their vision has changed by at least 0.5 dioptrine. Furthermore, the
National Committee of Doctors and SHI Funds determined that a patient is also entitled to new vision care products if his/her eyesight has improved by at least 20 per cent.

SHI patients over 18 years of age are subject to 20 per cent co-payment on bandages, inlays and aids used in compression therapy.

Since orthopedic aids usually require fitting, they are not subject to reference prices. The exact definition of a patient's entitlement in respect to these products is determined in contracts between SHI funds and the providers of these products and services.

Products of daily use that can also be used by healthy persons are not subject to coverage under the SHI system. The classification as a "product of daily use" is not affected if a product has to be modified and adapted for use by a handicapped person. However, SHI funds can cover some of the costs for modifying and adapting these products if the total costs of the product and its modification are greater than the costs of a normal product for daily use. In this case, the beneficiary pays the costs of the "product for daily use" while the SHI fund covers the costs related to the modifications.

As noted above, handicap aids and appliances of little or disputed therapeutic value as well as low-priced handicap aids are not subject to coverage under the SHI system.

When necessary, the SHI funds can request an assessment of the medical necessity of a handicap aid by the Medical Advisory Service (Medizinischer Dienst). The Medical Advisory Service can also provide counseling to patients.

Finally, SHI funds may also provide patients with handicap aids on a temporary basis.

3.2.7.4 Laboratory diagnostics

The term "diagnostics" encompasses reagents (i.e. in vitro diagnostics) as well as the technical equipment for analytic purposes that are used in the analysis of body fluids or tissue taken from the human body. Products that fall into this group include blood group tests and anti-body tests in the course of blood transfusions (e.g. hepatitis, HIV), the control of cancer (e.g. tumors and metastasis) and the measurement of risk factors for diseases (e.g. risk of heart attack), drug tests, the determination of pharmaceutical concentrations in blood, etc..

The products in this category are used both in doctors' laboratories and hospital laboratories for a number of important purposes: in the diagnosis of disease, to screen patients and thus prevent disease, to monitor the progression of disease, to follow therapy, to make prognosis about recovery, to provide objective information for Evidence Based Medicine, to select patients who are responsive to therapy, to detect predisposition for disease and for patient information. Many
of the products can also be used by patients themselves as self tests, including tests for the measurement of blood coagulation factors, the measurement of glucose levels in the monitoring of diabetes and pregnancy tests.

Laboratory diagnostics provide valuable information about the body’s functions and a patient’s state of health using minimally or non-invasive means. Furthermore, because they are performed in a test tube on samples taken from patients (in vitro means literally "in glass"), they do not come in direct contact with patients. Therefore, laboratory diagnostics are generally much safer for patients than many other medical devices used for diagnostic purposes.

According to German social health insurance regulations (SGB V §31 par. 1), SHI patients are entitled only to self-tests for the examination of urine or blood. There is no co-payment in such cases (SGB V, § 31 par. 2 sentence 2).

3.2.8 The Health Care Reform 2000 – Perspectives in the office based sector

The "Law for the Reform of the Social Health Insurance System in the Year 2000" contains a number of new provisions and regulations that could have far-reaching effects on the provision of care in the office-based sector.

Although the continuation of rigid budgets in combination with the strict adherence to the principle of stable contribution rates will tend to perpetuate the existing structural inefficiencies, some of the regulations offer new opportunities for increasing efficiency in the provision of health care.

One such measure is the regulation calling for contracts for the establishment of "integrated care". The contracts on integrated care, which can involve individual health care providers, groups of providers or regional doctors' associations have the potential to increase competition among providers and thus promote the efficient utilization of medical devices.

The new provisions under § 92 e of the German Social Code, Book V, which call for the direct participation of the national associations of medical device manufacturers in the promulgation of guidelines for the prescription of handicap aids and appliances, represent an important step towards integrating the legitimate interests of the medical device industry in those decision making processes that affect its products.

The introduction of new regulations for the pricing of services involving large medical equipment could contribute to increasing the transparency and efficiency in the provision of these services. However, it is important that the valuation of services is based on the medical benefits to patients
and not solely on considerations that focus on the distribution of funding in the ambulatory sector.
4 Medical devices: The perception of decision makers in the German health care system

4.1 Description of the survey

The perception survey of 23 decision-makers and opinion leaders in the German health care system was conducted between August and December 1999. The group of interviewees included representatives of political parties, social and private health insurance organizations, healthcare providers and patient groups. The interview was designed to elicit information on the participants' views on medical devices, the medical device industry and its role in health care. Furthermore, the survey included general questions on current problems in the German health care system and proposed solutions in the health policy discussion.

The interview-based process was not designed as a representative survey. Rather, its objective was to provide insight into the knowledge, views and opinions of key decision-makers with respect to the following topics and issues:

A. Medical devices and the medical device industry in general
B. The role of medical devices in the German health care system
C. Health care reform and its effects on the diffusion and coverage of medical devices

The interviews were based on a 12-page questionnaire containing 38 closed questions and 7 open questions. Each interview session was opened with a general description of the study and its objectives, but no prompting was made during the course of the interviews. A copy of the questionnaire with graphs of the results is included in the Annex.

4.2 Summary of the results

4.2.1 Views on medical devices and the medical device industry

In general, the interviewees were well informed with respect to medical devices and medical device manufacturers. Almost all participants could name at least three examples of medical devices. Furthermore, the answers indicated that the large majority of interviewees (88 %) are also well aware of the great diversity of medical devices. For example, more than half named medical dressings as well as computer tomography or nuclear spin tomography to indicate the broad spectrum of products that fall under the term "medical device". However, only one participant named in vitro diagnostics as an example of a medical device and as an example of an
important advance in prevention and diagnostics. These results suggest that most of the participants probably do not (yet) view in vitro diagnostics as medical devices.

The majority of the interviewees were also well informed with respect to medical device manufacturers. All participants could name at least one German manufacturer of medical devices. The most commonly named companies were Siemens, Dräger, and B. Braun. The most commonly named foreign manufacturers were Medtronic, St. Jude, and Toshiba. Only 16 per cent of the interviewees could not name a foreign manufacturer of medical devices.

The results with respect to innovations in the area of medical devices were varied. Less than one-third of the interviewees could name an example of an important advance in the area of prevention. Most of the answers were related to tertiary prevention, i.e. to measures aimed at avoiding relapses or recurrences of disease. Only two participants named examples of important advances in primary and secondary prevention.

However, almost all participants (96 %) could name at least one important innovation in the area of diagnosis. The items most mentioned were computer tomography and cardiac catheterization.

The participants were also well informed with respect to advances in the treatment of diseases: 96 per cent of the interviewees named at least one example for an advance in the treatment of diseases. The range of devices named was much broader than those named in the area of diagnostics. The technologies most often cited in this context included extracorporeal lithotripsy and coronary angioplasty. Other medical device technologies that participants viewed as important advances include dialysis, minimally-invasive surgical techniques and "computer controlled" surgery.

Roughly half of the interviewees could name important advances in the area of rehabilitation. Although many of the responses were rather general, e.g. orthopedic aids, they also included very specific technologies such as speech aids, simulators used in physical therapy, and digital control units for motorized wheelchairs.

With respect to the structure and composition of the medical device industry, 91 per cent of the interviewees believe that most medical device manufacturers are small- to medium-sized companies. Approximately 55 percent of the participants supported the statement that the majority of medical devices on the German market are the products of German companies.

More than three-quarters of the interview participants affirmed the statement that medical device manufacturers invest large sums in research and development. However, one-third of the
respondents also supported the statement that medical device manufacturers focus more on the marketing of their products than on their research and development. The majority of respondents also supported the statement that pharmaceutical manufacturers invest a greater share of their sales turnover in research and development than is the case for medical device manufacturers.

There was no clear dominance of a particular view in regard to the importance of medical device innovation: 50 per cent of the respondents supported the statement that most medical device innovations represent only marginal improvements, while 41 per cent viewed most innovations in the area of medical devices as important advances.

With respect to the pricing of medical devices, over 70 per cent of those interviewed consider the prices of medical devices to be too high. A slightly lower percentage of the respondents (67%) viewed the prices of pharmaceuticals as too high. Furthermore, 57 per cent of the interviewed participants supported the statement that "medical device manufacturers earn very high profits".

4.2.2 The role of medical devices in health care

Although almost all of the interviewees (89 %) supported the statement that new medical devices help save lives and improve the quality of life, many expressed the opinion that this statement applies only to certain cases and/or certain indications.

Eighty-three per cent of the respondents affirmed the statement that medical devices tend to lead to rising health care expenditures and not to spending decreases in the long run. Only 13 per cent of the respondents believed that medical devices have a cost saving effect in the health care sector. In regard to the reasons for the effects of medical devices on health care spending, 24 per cent of the respondents viewed patients' expectations as an important factor in driving costs while 67 per cent of the respondents supported the statement that cost increases are due to the fact that new medical devices don't replace existing technologies, but are used in addition to them.

The prices of medical devices were considered to play an important or very important role in increasing the costs of health care by 69 per cent of the survey participants. It is interesting to note in this context that the role of prices in driving costs was considered less important in the pharmaceutical sector, where only 55 per cent of the respondents viewed price developments as an important or very important factor behind cost increases.

The number of prescriptions was viewed to be an important factor behind increasing costs in both pharmaceutical and medical device markets: 86 per cent of the respondents considered the...
number of prescriptions of medical devices as an important cost-driving factor and 96 per cent of the interview participants viewed the number of pharmaceutical prescriptions as an important factor for cost increases.

The so-called "innovation" component was also viewed by the survey participants as an important cost driver in both medical device and pharmaceutical markets: 74 per cent of those surveyed viewed the innovation component as an important factor for cost increases in the medical device sector, while 83 per cent considered it an important factor in the pharmaceutical sector.

The answers to the question, "What percentage of medical devices prescribed or utilized at the expense of Germany's social health insurance system is medically necessary" ranged between 30 and 95 per cent, with an average of 73 per cent and mode of 75 percent.

4.2.3 Opinions on health care reform and reimbursement policy

The majority of the survey participants (55%) view the cost of health care in Germany as too high. However, 74 per cent affirmed the statement that the main financial problems of Germany's social health insurance system are not due to increases in health care expenditures but to the sluggish development of the system's revenue base. Furthermore, almost all of those interviewed (96 %) supported the statement that future health care reforms must address the problem of revenue generation in the social health insurance system. As a means for improving the revenues of the system, two-thirds of the survey participants proposed the expansion of the assessment basis to include additional sources of personal income or an increase in the assessment cut-off point. Other proposals for improving the revenues of the social health insurance system included the establishment of a compulsory basic insurance package with voluntary supplemental insurance, increasing the assessment threshold for pensioners and the unemployed to their former levels, fixing the employer's share in SHI contributions, and the introduction of a machine tax.

Many of the survey participants did not have detailed knowledge of the mechanisms for the finance and reimbursement of medical devices and the problems facing medical device manufacturers. However, 80 per cent of the respondents could name at least one medical device or medical procedure that is not covered by the SHI system. Only one-third of the respondents could name examples of medical devices that are covered by insurers in other countries but not by Germany's SHI system. This relatively low response rate is due largely to the fact that many interview participants were not aware of restrictions on the reimbursement of medical devices in countries other than Germany.
Although the majority of those interviewed (74%) supported the view that the diffusion of medical devices should not be subject to government controls, an equal share supported the statement that the diffusion of medical devices should be subject to control by the SHI system's committee for "joint self-management".

Government price controls on medical devices were rejected by 96 per cent of the interview participants, while 48 per cent supported the regulation of prices (e.g. through reference prices) by the National Committee of Doctors and SHI Funds. With respect to medical device manufacturers' participation in the review process of new and existing technologies, 76 per cent of the respondents supported the view that medical device manufacturers should only be granted a hearing in the process. The remaining 24 per cent supported granting medical device manufacturers the right to submit products for review by the committee, and none of the respondents believed that manufacturers should be granted voting rights in the decision-making process.

The majority of the survey participants did not feel that the changes in the hospital sector contained in the legislation for the "Health Care Reform 2000" would limit patients' access to new medical procedures. Only 9 per cent of the respondents felt that the general introduction of a hospital finance system based on lump-sum payments per case to cover all hospital services would restrict patients' access to new medical technologies.

The vast majority of respondents (70%) also saw no potential impediments to patients' access to new technologies in the establishment of a committee for the review of medical technologies in the hospital sector.

Although 78 per cent of the respondents considered budget measures an effective means for controlling health care costs, only 45 per cent believed that budget measures would not restrict patients' access to modern medical procedures in diagnosis and therapy.

Only 13 per cent of the respondents would be willing to accept the CE mark as the sole criterion for the reimbursement of medical devices. The vast majority of respondents (78%) supported the statement that new medical devices should only be covered by the SHI system when it has been proven that their use is associated with both medical benefits to patients and economic advantages to the health care system. When asked to name the kind of evidence necessary for this purpose, 55 per cent of those surveyed named health economics analyses. Approximately 40 per cent stressed the importance of clinical evidence as documentation of the medical benefits of new medical devices.
The majority of those interviewed were of the opinion that privately insured patients have quicker access to new medical technologies than socially insured patients, while 39 per cent felt that there is no difference in this respect between privately and socially insured patients.

4.3 Conclusions

Since the interviews were not designed to provide a representative survey, the results cannot be generalized. However, the answers do point to a number of interesting issues:

- In general, the decision-makers and opinion leaders included in the survey are well-informed with respect to the broad range of medical devices. Furthermore, they acknowledge the contributions medical devices have made towards saving patients' lives and improving their quality of life. However, when health care experts view the advances made possible through medical devices as marginal, there is an obvious need to communicate the breakthrough innovations of the past and the substantial innovative potential of the medical device industry. There seems to be a clear need for more information and education.

- The majority of those surveyed acknowledge the medical benefits associated with medical devices, but believe that these benefits are bought in many cases at a very high price. Although medical devices make up only a small portion of total health care expenditures, many of the survey participants view them as an important factor in the general increase in health care costs, as high priced and as too heavily utilized. The fact that less than 10 per cent of the interviewed experts underscore the cost saving potential of innovative medical technologies once again points to the need for targeted information campaigns.

- The CE mark alone is not accepted as proof of the medical quality of a product. Decision makers expect controlled clinical trials as evidence of the medical benefits of products and health economics analyses to document the effectiveness of new products and procedures. Technology assessment and evidence-based medicine are likely to play an even greater role in the access of medical devices to health care systems and their diffusion following introduction.

- Most decision makers feel that there is no need for expanding the rights of medical device manufactures in the review processes of the National Committee of Doctors and SHI Funds related to medical procedures and devices. In this context too, there is an obvious need for heightening the decision-makers' awareness of existing problems (e.g. lack of transparency, a monopolistic decision-making structure, slow decision-making processes, legal uncertainty) in order to reach rational solutions.
5 Medical devices and medical progress

5.1 Definition

5.1.1 How can medical progress be defined?

The term "medical progress" is used in a broad sense to describe the introduction of new procedures and products as well as the (qualitative) improvement of existing procedures and products. The reorganization of the whole health care system or of individual sectors in the health care system – for example, with respect to the finance and provision of services – is also subsumed under the concept of medical progress.

Medical progress in a narrow sense is defined as the refinement of diagnostic and therapeutic methods on the basis of expanded or improved experience, knowledge and abilities of the users.

In contrast to these concepts, the concept of "medical-technological progress" describes those refinements in diagnostic and therapeutic procedures that are based on new or improved medical technologies. There are two basic types of medical technological progress:

- Medical technological progress in the form of **product innovation** makes it possible to diagnose or treat diseases that could not be diagnosed or treated prior to the introduction of the new technology or which allow diagnosis and treatment at a lower cost than existing procedures. Product innovations thus increase the efficiency and the effectiveness of the health care system by improving outcomes and expanding potential services.

- The concept of **process innovation** is defined as the improvement of existing procedures. Process innovations generally increase the efficiency of the health care system by improving existing forms of diagnosis and therapy in terms of resource utilization.

In practice, it is difficult to distinguish between product and process innovations, because the two usually occur together. There are many examples of new and innovative medical devices that have revolutionized existing diagnostic and therapeutic possibilities (product innovation) and also resulted in a decrease in resource utilization per procedure or case (process innovation).
It is often difficult to determine whether medical progress in the broad sense is due to medical progress or medical technological progress. One reason for this difficulty is the fact that these types of progress are interdependent and develop parallel to each other, so that the separate analysis of each type of progress is inadequate for capturing their full effects. In many cases, the expanded knowledge of health care providers is the impetus for the development of new or improved technologies. Conversely, the development of product innovations and process innovations increases the knowledge of health care providers. In any case, medical technological progress is a key component in the development of health care systems.

5.1.2 Problems associated with medical technological progress

If one views medical technological progress solely from the medical perspective, it must be judged in general as beneficial, since it has positive effects on health promotion, the diagnosis of diseases and their treatment. From this perspective, all medical technological progress that has a positive marginal outcome should be incorporated in the provision of health care services. However, this vantage point ignores the - mostly financial and administrative - problems associated with the unfettered access and distribution of new technologies in a health care system. For even in those cases in which the medical benefits of a new technology are indisputable, it must not be forgotten that medical technological progress does not usually come cost free. In addition to the direct costs that result from the finance and reimbursement of a new technology, there are usually additional indirect costs in the form of opportunity costs.

There is therefore a need for the evaluation of medical technological progress to compare all expected costs of a new technology or procedure with the expected benefits. Such analyses are
generally classified as cost-benefit analysis in the broadest sense. In general, there are three types of economic evaluation in this sense:

- Cost benefit analysis
- Cost utility analysis
- Cost effectiveness analysis

Common to all three types of analysis is that a ratio is constructed relating an index of benefits (e.g. utility) to the estimated costs in order to arrive at an overall valuation of a technology. The effects of a technology (costs and benefits) can result directly from the use of a technology or may be an indirect result of its use. Furthermore, it may be easy to express benefits and costs in monetary terms (tangibles) or it may be necessary to use further tools to impute a monetary value. In some cases, intangible costs and benefits might not be measurable at all. On the basis of the above distinctions, costs and benefits can be classified in four categories: direct-tangible, direct-intangible, indirect-tangible, indirect-intangible (see Figure 5.2). The measurement and analysis of intangible values and costs can sometimes be very difficult and is usually subject to the subjective views of the analyst.

Health Technology Assessment (HTA) is defined as the systematic analysis of new and established technologies "with respect to their physical, biological (including the strictly medical), social and financial effects".¹
### Figure 5.2 Cost and benefits of a therapeutic or diagnostic procedure

<table>
<thead>
<tr>
<th>Type of effect</th>
<th>Measurability</th>
<th>Costs</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct</td>
<td>Tangible</td>
<td>- operating costs</td>
<td>- avoidance of additional costs due to disease, ...</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- administrative costs</td>
<td>- avoidance of sick pay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- labor costs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- personnel costs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intangible</td>
<td>- temporary impairment of the patient’s subjective well-being / pain and discomfort of diagnostic or therapeutic procedure</td>
<td>- immediate success of treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- avoidance of future impairments to patient’s well-being</td>
</tr>
<tr>
<td>Indirect</td>
<td>Tangible</td>
<td>- temporary sick leave of the patient</td>
<td>- avoidance of future loss of social security contributions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- reduction in productivity</td>
<td>- reduction in sick pay through lower risk of contamination of others at workplace</td>
</tr>
<tr>
<td></td>
<td>Intangible</td>
<td>- temporary removal of the patient from his/her social environment (family, friends)</td>
<td>- maintenance of social contacts</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- loss of an optimistic view of life</td>
<td>- benefits from activities that would be otherwise impossible</td>
</tr>
</tbody>
</table>
Figure 5.3  Classification of medical and medical-technological progress

<table>
<thead>
<tr>
<th>Result</th>
<th>Resource use</th>
<th>less</th>
<th>unchanged</th>
<th>more</th>
</tr>
</thead>
<tbody>
<tr>
<td>improved</td>
<td>Type A</td>
<td></td>
<td></td>
<td>Type C</td>
</tr>
<tr>
<td>unchanged</td>
<td>Type D</td>
<td></td>
<td></td>
<td>Type E</td>
</tr>
<tr>
<td>poorer</td>
<td>Type F</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

From the health policy perspective, the most interesting type of medical progress is that which leads to improved results with less resource utilization (Type A).

As a rule, innovations that fall under the categories of Type B, D and E are usually accepted without reservation since they have positive effects on the market for health care. The expansion of diagnostic or therapeutic methods increases competition among manufacturers and health care providers have a broader range of products from which they can choose that which is best suited to patients' needs. Both of these effects tend to lead to overall cost savings in the health care system.

Type E progress represents a borderline case since it results in an expansion of diagnostic and therapeutic options without affecting resource use and results.

The assessment of innovations that have both positive and negative effects on resource use and/or results is more problematic: Those types of medical and medical-technological progress that lead to improved results through an increase in resource utilization (Type C) as well as those innovations which reduce resource utilization and produce poorer results (Type F) require more differentiated analysis. In general, innovations that fall under the category "Type F" will tend to be considered politically undesirable and will not be promoted by anyone in the health care system (although payers may promote such innovations in exceptional cases).

In practice, medical-technological progress of the Type C (which often takes the form of product innovation) tends to be subject to the most contention in health policy, since it is caught between the divergent interests in the health care system. On the one hand, it is considered politically and socially intolerable that patients do not have access to new or improved diagnostic and therapeutic procedures, since "health" and the protection against disease is viewed as one the
most valued goods. On the other hand, the use of the procedure could be the source of conflict, since it involves an increase in the use of resources that are then no longer available in the rest of the health care system and in other related areas thus creating opportunity costs.

Without doubt, there is a need for methods for the evaluation of new diagnostic and therapeutic procedures. However, there is a fundamental problem in the evaluation of medical and medical-technological progress: the need for an evaluation of a product or procedure is particularly acute when they are newly developed and about to be introduced into the market. At this point, however, little valid cost benefit data is available for such products and procedures since well-founded analysis and conclusions can only be made in the course of their application.

The access of medical-technological advances that represent process innovations is easier due to the types of spending constraints in the health care system. In such cases, innovative procedures and products increase efficiency, thus allowing attainment of a given objective with less resource utilization and less cost to the health care system. However, there may be problems in the introduction of technologies with a high initial price tag but significant future savings, as the broad potential application of these technologies could overtax the financial capacities of the social health insurance system and employees/employers.

The objective of "stable contribution rates" has been a central principle of Germany's social security regulations since the 1970s (§ 71, §141 SGB V). However, this objective is based primarily on non-medical criteria (employer's contribution, unemployment, compulsory nature of SHI contributions). Whether patients' willingness to pay under market conditions would result in more or less funding for health care is a question to which there is yet no answer.
5.2 Access of new procedures and products (to the ambulatory sector) under different types of reimbursement controls

5.2.1 Budgets

The term budget is usually defined as "the prospective limitation of financial resources for a certain time period". The term includes different types of budgets such as fixed budgets, flexible budgets and spending caps. At present, both flexible budgets (e.g. "standard service volumes") and fixed budgets (e.g. the pharmaceutical budget and the budget on laboratory services) are applied in the ambulatory sector. In addition, spending in the ambulatory sector is subject to a sectoral budget that restricts total expenditures on the services of office-based doctors. Another type of budget that was under discussion in Germany is the so-called global budget, which restricts the total expenditures of an SHI fund without limiting expenditures on a particular sector of the health care system.

Under a fixed budget, health care providers can vary either the number of services or the average cost of each service. These options are illustrated by the following example. Assuming a fixed budget of DM 1000, a health care provider can – in the extreme cases – either provide a) one service costing DM 1000 or b) 1000 services costing DM 1 each. If the number of services provided is increased, the price per service falls in proportion to the increase in quantity (see Figure 5.4).

With each increase in the number of services, their provision becomes less profitable for the healthcare provider. If the average price per service falls to a level that is at or below the level of average costs, the health care provider will no longer be willing to provide the service.
Fixed budgets cannot be maintained for long in a growing economy since they lead to a continuous decline in prices and inevitably to the strict rationing of services. With respect to product innovation, fixed budgets act as a hindrance to progress and diffusion and thus counter the lawmakers' overall objective of promoting medical-technological progress.

Flexible (soft) budgets have a different effect. The periodic expansion of budget limits leaves room for the introduction of more cost-effective diagnostic and therapeutic procedures. The rate of medical-technological progress in the form of product innovations therefore tends to be greater than under fixed budgets. Payment per case (*Fallpauschalen*)

### 5.2.2 Payment per case

While fees based on payment per case (*Fallpauschalen*) are applied nationwide in Germany's hospital sector, this instrument has been applied in the office-based sector in rudimentary form only. Although social security regulations call for the definition and establishment of fees for "service groups" (*Leistungskomplexe*) as the basis for the remuneration of office-based doctors' services, the doctors' fee schedule remains a compendium of individual services.

The following section discusses the effects of payment per case on medical progress and medical-technological progress. Figure 5.5 shows a model of a treatment pathway comprising four different services (L1 – L4). The average fee per service is calculated by dividing the total fee by the number of services. For example, a payment per case of DM 100 results in an average fee per service of DM 25. Since each service in the model is associated with different costs, the profit (or
earnings) per service differs (yellow area). The total profit (earnings) of the health care provider for the case is equal to the sum of the profits (earnings) per service.

**Figure 5.5  Payment per case – before innovation**

It is necessary to differentiate between process and product innovation in order to understand the effects of innovation. In general, process innovations lead to a reduction in costs in the health care system. From the perspective of the healthcare provider, the application of process innovation is therefore unproblematic. However, it is assumed in this model that the product innovation associated with the service L4 leads to higher costs for the health care provider. In order to maintain total profitability of the healthcare provider, the cost increase associated with the product innovation must be compensated by cost-saving innovations in other services (L1). If this is not the case, health care providers will tend not to provide treatment at this per case fee.

In the example shown in Figure 5.6, the savings represented by innovation in service 1 more than compensate the additional costs associated with the innovation in service L4. Thus the service becomes more attractive to the health care provider.
In the long run, process innovation can have drawbacks for health care providers since they could result in a downward adjustment of the level of payment per case. Overall, however, payment per case gives health care providers considerable incentives to invest in resource saving technologies.

5.3 Patients' access to new medical devices

5.3.1 The ambulatory sector

In principle, doctors in Germany who provide care in the ambulatory setting are not subject to therapeutic guidelines or recommendations in the sense of codified standards. As a result the “clinical freedom” of doctors is largely unfettered by regulation.

According to the lawmakers' view, however, new procedures and services that are provided under the coverage of the SHI system must have clinical or economic advantages over existing procedures. This assumes that innovative procedures have already been subject to an evaluation process before they can be admitted to the benefit catalogue of the SHI system.
This evaluation process of medical and medical-technological innovation in the ambulatory sector is currently the responsibility of two committees:

- The Working Committee for Medical Procedures (Arbeitsausschuß ärztliche Behandlung, the former "NUB-Committee"),
- The EBM Committee

The Working Committee for Medical Procedures is a sub-committee of the National Committee of Doctors and SHI Funds. The national committee's responsibilities include "the determination of guidelines for guaranteeing the adequate, appropriate and economical care of patients" (§92 SGB V).

The relevant passages of social law specify the tasks of the committee as follows: "In particular, the committee shall promulgate guidelines on the introduction of new diagnostic and therapeutic procedures".

The Advisory Council for the Concerted Action in Health Care defines the term "new procedures" as follows:

"New procedures are those that are not yet part of standard medical procedure and which differ notably from established procedures, or established procedures that are applied to a new indication."

Both the 2nd Law for the Reform of the SHI System (2. GKV-NOG) and the legislation that went into effect at the beginning of the year 2000 contain provisions for the establishment of additional Health Technology Assessment bodies. In the course of these legal changes, the above-mentioned NUB Committee was reconstituted and given its present title. In addition to the change in name, the committee was given additional responsibilities under the 2. GKV-NOG: first, it can review procedures that are already part of the benefit catalogue on its own initiative; second, it is supposed to focus also on the "clinical efficacy" of procedures. Prior to implementation of the law, the latter task was the responsibility of the EBM Committee.

According to § 135 of the German Social Code, Book V, new diagnostic and therapeutic procedures can only be introduced into the general benefits catalogue when the procedure has passed the review of the Committee for Medical Procedures. The right to propose a new procedure for review by the committee is restricted to the National Association of Office-Based Doctors, the regional associations of office-based doctors and the SHI funds.

According to the social security regulations, the recommendations of the Committee for Medical Procedures focus on:
1. The diagnostic and therapeutic benefits as well as the medical necessity and economic characteristics (e.g. compared with established methods) of a procedure.

2. Measures to ensure the proper application of the new procedure (doctors' qualifications, needs and requirements of quality assurance).

3. The documentation requirements.

The national committees review procedures only on the basis of the criteria under point 1. If the result of this review is negative, the procedure in question is usually not subject to coverage under the SHI system. However, in exceptional cases the national committees may make positive decisions on procedures that do not fulfill all of the criteria listed under point 1 (§135 par 2 SGB V).

The process of filing an application for the review of a new procedure or product is subject to certain formalities. A complete application must contain a basic description of the procedure (especially in the context of the intended indication), information on its medical value and medical necessity and an economic comparison with existing procedures.

Following a positive decision by the working committee, the EBM Committee determines the number of points for a procedure. The legal basis of this task is specified in § 87 para. 2 SGB V as follows:

"The doctors' fee schedule (einheitlicher Bewertungsmaßstab) defines the contents of covered services and their relative value in points. The standards of measurement are to be reviewed periodically with respect to the definition of the service and to their relative value and to determine whether they meet the current standard of medical science and technology and the requirements of rationalization in the context of the economical provision of health care."

If a consensus is not reached in the EBM committee, the committee membership can be expanded to include four non-partisan members and a non-partisan chairman. The expanded committee then makes a binding decision whether the procedure can be covered by the SHI system and determines its definition and relative point value.

The following figure provides an overview of the complex administrative procedure involved in granting coverage to new medical procedures in the ambulatory sector.
The use of the new diagnostic or therapeutic procedure in the ambulatory sector is covered on the basis of the EBM.
5.3.2 The hospital sector

5.3.2.1 The "Ausschuss Krankenhaus"

In the past, hospital doctors have been free to use the therapy of their choice. Basically, the choice of therapy is led by medical, economic and personal motives. Under the provisions of the Health Care Reform 2000, the German Chamber of Doctors (Bundesärztekammer), the national associations of the Social Health Insurance Funds (Spitzenverbände der Krankenkassen) and the German Hospital Federation are now responsible for the creation of a committee that is to review procedures used in the hospital sector (Ausschuss Krankenhaus - Hospital Committee). All forms of treatment and procedures (ie new and existing procedures) that are provided in the hospital sector can be reviewed by this committee. In order to review a procedure, the committee must be requested to do so by one of the following organizations:

- a national association of a Social Health Insurance Fund,
- the German Hospital Federation or
- a national association of hospital owners.

The review process is supposed to determine whether a method is necessary for the sufficient, appropriate and efficient provision of health care to the insured in the context of the whole health care system. If these criteria are not fulfilled, the method may not be used in hospital treatment provided to patients insured by the SHI system. The Hospital Committee can use a data base that is to be established by the German Institute for Medical Documentation and information (DIMDI). The data base will contain a survey of national and international studies of technology assessment in health care.

The Hospital Committee consists of 19 members. The national associations of the SHI Funds, the German Hospital Federation and the German Medical Chamber must agree on the statutes and procedures of the committee by August 31, 2000. If an agreement is not reached by this date, the statutes and procedures of the committee will be determined by the Ministry for Health.

The "Ausschuss Krankenhaus" is the counterpart to the "Bundesausschuss der Ärzte und Krankenkassen " in the ambulatory sector, which was established in 1998. The committees have similar functions and work plans. Furthermore, the evaluation results of both committees are to be coordinated in the future by the Coordinating Committee (Koordinierungsausschuss).
It is likely that the same criteria for technology assessment will be used in both the hospital and office-based sectors of the German health care system. The following figure lists the criteria that have been used in the office-based sector for the past two years:

**Health Technology Assessment in Germany**

**Utility:**
- Evidence of efficacy in the indication declared
- Evidence of therapeutic consequences of a diagnostic method
- Consideration of utility and risk
- Assessment of desired and non-desired outcomes
- Utility compared to other methods with the same purpose

**Medical necessity:**
- Importance of the medical range of application
- Frequency of the disease to be treated
- Course of disease without treatment
- Diagnostic and therapeutic alternatives

**Efficiency:**
- Cost-estimate for a single patient’s treatment
- Cost-utility considerations with respect to a single patient
- Cost-utility considerations with respect to the insured community (including an estimate of follow-up costs)
- Cost-utility considerations compared to alternative methods

Using a catalog of criteria derived from Evidence-Based Medicine (EBM), scientific criteria can be applied to the evaluation of medical procedures with respect to their medical utility and medical necessity. Due to the different types of hospitals in Germany, however, a single general evaluation of the efficiency of a treatment procedure in the hospital sector as a whole is hardly feasible. At least experience in other economic sectors suggests this conclusion. Therefore, the evaluation of the economic characteristics of a procedure should be decentralized and should consider the effects of a technology or procedure in the context of a given hospital. The "Ausschuss Krankenhaus" should focus its review of medical procedures on their utility and medical necessity.

In order for the results of the review process of the Hospital Committee to be useful, it is important that the process be performed quickly so that the pacesetter role of hospitals in the diffusion of medical innovations can be ensured. If a new or existing treatment method is judged positively by the "Ausschuss Krankenhaus", the question of the reimbursement of the method must be
answered promptly. It will therefore be necessary that the Hospital Committee act in close cooperation with the committee that will be established for the review and adjustment of the new system of hospital rates that is to be introduced in 2003.

5.3.2.2 Clinical Guidelines

The use of clinical guidelines in the treatment of patients represents an indirect means for the control of medical-technological progress. In Germany, the "Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften" (AWMF) develops uniform guidelines for different healthcare providers. The AWMF thereby competes with the medical chambers (Ärztekämmern), which also claim responsibility for the development of clinical guidelines.

In principle, the Social Health Insurance funds support the establishment of clinical guidelines. They believe that clinical guidelines will reduce the amount of healthcare services that are not medically indicated and consider guidelines the most important measure for improving efficiency in the provision of health care.

The task of the so-called Coordinating Committee is to use Evidence Based Medicine to develop criteria for the appropriate and efficient provision of health care for at least 10 diseases per year. The provisions of the Health Care Reform 2000 call for the Coordinating Committee to select diseases for which there is evidence that the existing forms of treatment are insufficient, incorrect or excessive and for which the amelioration of such inadequacies would have lasting effects on morbidity and mortality in the population. The guidelines will be obligatory for the SHI funds, hospitals and office-based physicians. Over time, the work of the Coordinating Committee can be expected to result in the more general application of guidelines in the provision of health care.

With its responsibilities for the development of clinical guidelines and for the coordination of technology assessment in the hospital and office-based sectors, the Coordinating Committee will be an important factor in the diffusion of medical technology. The specific tasks and procedures of the committee will be determined by the committee members themselves and laid down in the committee's statutes.

The 20 committee members represent

- the national associations of office-based doctors and dentists,
- the German Medical Chamber,
- the German Hospital Federation and
- the Health Insurance Funds.
Members will also include the chairman of the “Bundesausschuss der Ärzte und Krankenkassen” and the chairman of the Hospital Committee.

Guidelines on the basis of the Evidence Based Medicine (EBM) do not represent a direct restriction on the provision of health care to patients. As long as guidelines are subject to regular review and are adjusted to reflect medical developments, they do not represent a significant hurdle to medical and technological innovation in the health care system. In the foreseeable future, it is likely that such mandatory guidelines will be developed for only a few narrowly defined indications.

In the future, however, it is likely that there will be more standardization and more international harmonization in the specification of indications for which certain medical devices may be used. It is also likely that laboratory medicine will be particularly affected by these developments. In the interest of providing optimal health care, efforts must be made to include all available scientific knowledge in this process. The aim should be to handle each method fairly in the development of clinical guidelines.

5.3.2.3 “Centers of Excellence”

The rapid expansion of the medical sciences promotes the development of specialized healthcare facilities. Such facilities master the diagnostic and therapeutic approaches for providing care to patients with certain diseases. They are so-called "centers of excellence" for the treatment of these diseases.

In Germany, the prevailing notion that university hospitals must be versed in the whole spectrum of medical knowledge and services is colliding increasingly with financial limitations. As a result, university hospitals have already begun to specialize. They concentrate on one or a few specialized fields and try to take gain a leading position in these fields.

With respect to the provision of health care in Germany, the increasing specialization of large hospitals has resulted in the concentration of certain services at a few sites in Germany or in Europe. Patients must therefore travel longer distances in order to get specialized care. However, specialization also has advantages: For example, hospitals with more experience in the treatment of rare diseases usually have better treatment results than other hospitals.

In the future, cooperation among healthcare providers, health insurers and manufacturers in the context of "centers of excellence" will grow more important for the introduction of new highly specialized technological innovations. Only such centers of excellence have the equipment and the experience for the first application of innovative products in a large patient collective. Based
on their reputation, the findings of the "centers of excellence" will grow in importance for the diffusion of innovative medical devices in other hospitals.

There are not yet any official "centers of excellence" in Germany, but it is likely that the general criteria for such centers will be defined in the near future. In the medium-term it is conceivable that health insurers will only allow the use of very complex special technologies only in such "centers of excellence". These hospitals will then play a key role in the introduction of innovative medical devices and technologies in the hospital sector.


6 Coverage and reimbursement of medical devices in the German health care system: case studies

6.1 Introduction

This chapter presents selected cases as examples of the value and contribution of innovative medical devices to patients' health and to society as a whole. Particularly in the last years of the 20th century, we witnessed innovative breakthroughs both in the so-called "commodities" (e.g. wound dressings in the care of chronic wounds) and in the area of high-tech medical equipment. Important new developments can be found across all product groups, developed by hundreds of companies – from small specialty companies, through the many medium-sized firms to companies operating on a world scale.

This chapter provides examples of innovative medical technology from different product groups (medical-surgical instruments, hospital supplies, implants, laboratory diagnostics, wound dressings). All products have the potential to contribute substantially to the improvement of health care. These innovative procedures open new diagnostic and therapeutic possibilities. The advances they represent are not only experienced by patients, they are also measurable in terms of improvements in the chances of survival, increased life expectancy and better quality of life.

Contrary to the view that society is bound in a "progress trap" and medical technology contributes considerably to cost increases in the health care system, innovative medical devices provide the basis for cost effective or cost neutral progress. Often – as many of the following cases demonstrate – the rational application of advances in medical technology leads to clear savings in the treatment and diagnosis of diseases.

However, the introduction of innovative products is often hampered by financial problems of the health insurance system. The social security institutions, in particular the social health insurance system (SHI), are not able to or refuse to fund procedures that do not yet correspond to the "generally recognized state of medical knowledge". Here the question arises: Who decides when and on the basis of which criteria what the standard is? The present study attempts to provide ideas and solutions to this general question (see Chapter 7).

The following case studies are intended to outline the actual problems that manufacturers of innovative procedures and technologies must deal with when they introduce their products into the German market. These case studies show that the existing reimbursement rules and regulations governing the coverage of innovative medical devices in Germany make it increasingly difficult, and in some cases impossible, for patients to benefit from these advances. It
is in the interest of all to ensure that the German health care system remains open to such medical and technical advances, so that the progress remains available as soon as possible for all patients.

The first case study deals with the optimal care of chronic wounds. It shows the patient benefits and the economic advantages of modern wound care products in the treatment of chronic wounds. Unfortunately, the fee schedule for doctors in Germany does not differentiate between traditional wound care dressings (with lower unit prices) and modern advanced wound care products (which have higher unit prices). Since the reimbursement of the physician includes material costs, physicians earn less when they apply modern wound care dressings. A separate code in the doctors’ fee schedule EBM for the treatment of chronic wounds with modern wound care products could solve this problem. Alternative measures for ensuring the adequate use of modern wound care products would include:

- the consideration of their costs in regional agreements on general practice supplies and
- the abolition or loosening of budget restrictions on services associated with the treatment and care of chronic wounds.

**Low-pulsed ultrasound therapy** for the treatment of non-healing bone fractures was denied coverage in the office-based sector by a decision of the Federal Committee of Physicians and Health Insurance Funds in April 1999. Despite success rates of approximately 90%, the associated savings potential and a rebate warranty for cases in which the therapy fails, the SHI funds cannot pay for the treatment, even though individual SHI funds are willing to pay. From the patient's perspective, the only solution is self-payment.

The long, non-transparent and monopolistic decision-making process of the federal committee underscores the need for faster and above all more transparent structures in the self-management of Germany's health care system.

Legal considerations are also the central issues with respect to the reimbursement of visco-supplementation for the treatment of osteoarthritis of the knee, which is used primarily by orthopedic surgeons in office-based practice. Until 1997, the hyaluronic acid products used for visco-supplementation were authorized as pharmaceuticals thus subject to full reimbursement. New, improved preparations now fall under the medical device law, so that there is no legal obligation for the SHI funds to cover these products. At present, the SHI funds argue that these products are not covered, because medical devices are not mentioned in the German Social Code and refuse to cover the costs of these products. Patients, whose benefit from injections of hyaluronic acid include less pain and increased mobility, must pay for the treatment themselves.
A solution to this problem could be to allow more use of the products on a case-by-case basis in preparation for a general coverage decision for clearly defined indications.

For some time, uterus balloon therapy has been established in the treatment of therapy-resistant dysfunctional uterine bleeding (DUB). As an alternative to hysterectomy and the "classical" methods of endometrium ablation (with laser, loop or roller ball), uterus balloon therapy has clear patient benefits and enormous economic advantages, e.g. reduction in hospital stay and sick-leave days.

This procedure is unlikely to gain broad acceptance in Germany's hospital system, because the present payment system does not "reward" the advantages of minimally invasive procedures vis-à-vis existing alternatives. Uterus balloon therapy is only one example of many in which it is evident that minimally invasive procedures, paid for on the basis of per diem hospital rates, are economically uninteresting for hospitals. Due to its simple and safe application, the uterus balloon therapy is particularly suitable for the ambulatory sector. However, the procedure is not yet in the doctors' fee schedule. In order to be subject to general coverage, a national committee of physicians and health insurance funds must first decide on the procedure. The committee put uterus balloon therapy on the list of procedures for review in September 1999.

Coronary heart disease and acute myocardial infarction are the most frequent causes of death in Germany. Between 1980 and 1997, advances in medicine and medical technology helped lower the number of deaths due to these causes by almost 30 percent.

Percutaneous transluminal coronary angioplasty (PTCA) has been available as a means for the treatment of coronary artery disease since 1977. Since 1999, budgets and flat rates for material costs limit the potential for shifting routine PTCA from expensive hospitals into day-case centers. The PTCA case study demonstrates the need for a reimbursement system that is based less on sectoral differences than on quality assurance issues and the need for more efficient infrastructures. A further problem associated with fixed rates for material costs is that all material costs of advanced technologies (e.g. stents, brachytherapy, gene therapy, hemostatic wound closure systems etc.) cannot be charged separately, but must be covered by the general flat rates for material costs. Such forms of payments cannot accommodate the rapid developments in interventional cardiology for an extended period of time.

The primary objective in the treatment of cardiac arrhythmia is the avoidance of sudden cardiac death. Until the 1990s, the standard therapy for tachycardia management was based almost solely on pharmaceutical treatment. Today, the implantation of a cardiac defibrillator (ICD) is clearly indicated for certain conditions, and is gaining acceptance as a means of "primary prevention".
In accordance with the hospital rate ordinance, implantable defibrillators are paid for in Germany on the basis of special procedural rates and reduced per diems. The problem in the reimbursement of ICDs is less one of insufficient funding than of SHI funds' refusal to cover the costs of ICDs as a preventive treatment for patients who are at a high risk of sudden cardiac death. It is without doubt desirable that the SHI funds take measures to ensure that these patients can also benefit from the advantages of ICD therapy, especially since the mid-term to long-term cost effectiveness of ICD therapy is better than all other alternatives.

Minimally invasive GDC therapy is becoming increasingly established as a means for the treatment of intracerebral aneurysms. The total costs of treatment with the GDC procedure are considerably lower than the costs of surgical treatment.

However, the reimbursement situation in the treatment of intracerebral aneurysms is an example of how Germany's hospital finance system can hinder innovation. Neurosurgical procedures are typically covered by per diems and there are therefore no incentives to reduce the hospital length of stay. This makes it difficult, if not impossible, to fund minimally invasive procedures such as the implantation of a GDC coil.

Current hospital regulations allow for the use of "trial projects" as a means for negotiating adequate fees for new medical procedures. Unfortunately, it is becoming increasingly difficult to negotiate such trial projects. Without such financial incentives for hospitals, however, many innovative and cost-effective procedures will not be introduced into the hospital sector.

Innovation in the area of in vitro diagnostics has led to the development of new tests with higher specificity and sensitivity than many existing diagnostic options. Furthermore, some of the new tests not only provide better results, they provide them faster and with cost-saving effects, as the examples of screening for chlamydia trachomatis infections and the early detection of prostate cancer demonstrate.

The reform of laboratory reimbursement introduced in July 1999 may be an appropriate means for limiting expenditures in this area. However, due to the lack of quality assurance measures, the reform has led to a situation in which necessary special laboratory tests – to which many of the new testing methods belong – are not being performed or are being shifted into the more costly hospital sector.

Laboratory testing based on guidelines and quality assurance measures should ensure that modern laboratory procedures remain accessible to all patients. The less invasive, early and reliable diagnosis of disease benefits not only patients, but can also result in considerable cost savings in the health care system as a whole.
The following case studies provide compelling examples of the enormous advances in medical science and medical technology. Since these and other new procedures and technologies lead to improved care for patients, it is in the interest of all to ensure that these innovations find their way into the Germany health care system. This will require more transparent and evidence-based decision making processes that allow for quick evaluation and coverage decisions for innovative technologies.
6.2 Case study 1: Modern wound care

Approximately 4 million people in Germany suffer from chronic wounds, i.e. wounds that are usually due to a circulatory or metabolic problem do not heal spontaneously.

Chronic wounds, also known as "open legs" or "bed sores" represent a substantial restriction in the quality of life for patients: they are associated with pain, limit mobility and can also lead to social isolation.

Traditional therapies for the treatment of chronic wounds are based on topical treatment and dry dressings. This form of therapy is not only labor intensive, but requires a frequent change of dressings that disturbs the healing process.

Modern procedures for the treatment of chronic wounds are based on "moist" wound care and are designed to support natural healing processes. In comparison to the conventional, dry treatment, they often accelerate the healing process considerably. This simple and largely pain free way of changing dressings - which must not be performed as often as with dry dressings – represents a clear benefit for patients, caregivers and physicians.

Despite these advantages, moist wound treatment is not very widespread in Germany. An important reason for the limited application of these therapies is that they are not included in the doctors' fee schedule, where the fees are calculated on the basis of traditional dressing materials.

Although modern wound care methods lead to substantial cost savings in the care and treatment of chronic wounds, the modern wound care products are often not used due to their higher unit cost prices. The consequences are longer healing times for patients and thus higher total costs for the health care system.

6.2.1 Wound care: Objectives and applications of wound care products

Patients with chronic wounds represent a growing problem in the health care system. In particular, the changing age structure in the population will lead to an increase in the number of patients with chronic wounds.

A differentiated wound care strategy should provide optimal support to the natural healing process. Based on the different causes of poorly healing wounds, local wound care pursues essentially two goals: the cleaning of the wound (both surgical and physical measures can be used) and the promotion of new tissue formation. Local wound care represents a major share of the therapy of the most difficult problem wounds, in particular ulcus cruris, decubitus, burns, abscesses and excisions. Depending upon the kind of wound, its size and the stage of the healing, two different wound care methods are recommended:

- the conventional "dry" wound care and
- the physiological wound care in the damp environment, also termed "moist" wound care.
6.2.1.1 Dry wound care

"Dry wound care" denotes wound care based on dressing wounds with dry dressing materials, e.g. with gauze bandages or with absorbent bandages and compresses. The prime task of the dry dressing is to protect the wound and absorb wound secretions. The traditional absorbent gauze still plays a role in modern wound care. The main applications for the dry wound care are the treatment of primary wounds, minor injuries restricted to a small area small and wounds for which the formation of a scab is desired and/or tolerable.

With conventional dry wound care there is always the danger that wound secretions cause the bandages to adhere to the wound itself. Due to the type of materials used, particles from the dressing material are frequently deposited in the newly formed tissue and retard the healing process. Dry wound dressings must be changed frequently each day.

6.2.1.2 Moist wound care

An efficient moist wound care must fulfill two purposes at the same time: it must remove secretions and supply and/or retain moisture. The applications for such new hydroactive wound care products include acute and chronic wounds with reduced, disturbed or retarded healing. They are suitable in particular for the treatment of secondary wounds, where the prime objective is to fill the wound through the formation of new tissue. Superficial wounds (e.g. scratches and scars resulting from the removal of tissue for transplant purposes), in which a moist wound surface is a condition for unhindered healing, should be treated solely on the basis of moist wound care products.

Modern interactive wound dressings can be divided into the following groups:

- alginates,
- bio-regulatory wound dressings,
- foil dressings,
- hydrogels and hydrofibers,
- hydrocolloids,
- laminate dressings,
- foams.

Ideally, products for moist wound care should fulfill the following performance requirements:

- maintenance of a moist environment for the wound,
- removal of surplus wound fluids and toxins,
- allowing for gas exchange,
- thermal isolation of the wound,
- protection from secondary infections,
- protecting the wound from foreign particles or toxins,
- permit dressing changes without additional wound trauma.

In comparison to conventional dry wound care, moist wound management often leads to a substantial acceleration of the healing process. Besides the therapeutic effect, the simple and to largely pain free change of dressings is a clear benefit to both patients and healthcare providers.

For the patient, the pain reduction and the improved comfort are important. Due to the more rapid wound healing and the reduction in the number of dressings changes, moist wound management proves itself more cost effective than dry wound care. However, moist wound care is not well known and is only by approximately ten per cent of the physicians on a regular basis.

### 6.2.2 Epidemiological and socioeconomic data on chronic wounds

It is estimated that some 4 million patients in Germany suffer from various forms of chronic wounds. The most common forms of chronic wounds are ulcus cruris, decubitus (bed sores) and the diabetic foot.

#### 6.2.2.1 Ulcus cruris

According to data of the SHI funds nearly 2.5 million patients suffered from an ulcus cruris in 1991. With a prevalence of approximately 1 per cent of the population and 4-5 per cent of the population over 80 years of age, it is estimated that approximately 1 to 1.5 million persons suffer from ulcus cruris venosum. Ulcus cruris venosum represents the most frequent cause of chronic wounds and approximately 60-80 per cent of all chronic ulceration (arterial ulcer: 4-30%, mixed arterial venous ulceration: approx. 10%, remaining forms: approx. 10%)⁵.

More than 2 million days of sick leave and 1.2 million hospital days were due to ulcus cruris in 1991. The annual treatment costs are estimated at 2 to 2.5 billion DM.⁶

#### 6.2.2.2 Decubitus

According to estimates of the prevalence of decubitus in Germany, this type of wound affects at least 5% of hospital patients and 1% of the population, i.e. between 800,000 and 1 million cases.
In addition to hospitals, decubitus often affects in nursing home patients and patients in domestic care, since about 70% of the affected patients are elderly.

The costs per case, which result in particular from a longer length of stay in the hospital, range on the average between DM 3,000 and 12,000. For all of Germany this implies total costs of between 1.5 and 4 billion DM each year. The estimated potential savings through standardized prevention and therapy – of which improved wound management is a substantial component – range between 0.75 and 3 billion DM.

6.2.2.3 Diabetic ulcers

Approximately 1 million patients in Germany are at risk of suffering from diabetic foot ulcers. Roughly 15 per cent of all diabetics develop foot ulcers and 3 per cent a diabetic foot.\(^7\)

It is estimated that 25 per cent of the costs for the treatment of diabetics are due to foot complications.\(^8\)

6.2.3 Therapeutic wound management

The therapeutic management of ulcers and decubitus usually includes a range of measures. In addition to topical treatment the illnesses leading to the ulceration must be treated. With ulcer cruris this typically occurs on the basis of:\(^9\)

- compression therapy,
- surgical treatment,
- sclerotherapy,
- the treatment of exogenous factors.

In the case of decubitus, preventive measures such as the avoidance of pressure spots and supporting measures play an important role. The treatment usually includes the following elements:\(^10\)

- regular relief from pressure spots,
- management of risk factors,
- local wound care,
- surgical measures.

Local wound treatment plays an important role in the treatment of all types of chronic wounds.
6.2.4 Modern wound care: Data on efficacy, quality of life and efficiency

As in many other areas, there is little well-founded data in Germany on the topic of chronic wounds. Epidemiological figures are based on estimates and it is not known how many cases of decubitus are treated in hospitals, how they arise and what it costs to treat them.11

6.2.4.1 The efficacy of modern wound care products

There are a number of modern wound care products that can be applied during different stages of the healing process. Comprehensive clinical studies and case studies of the efficacy have been conducted for many of these products in the hospital sector, ambulatory sector and in the provision of long-term care.12, 13 Comparisons of the traditional and modern wound care products in the management of problem wounds reveal the advantages of the modern, moist treatment methods.14

6.2.4.2 Patient benefits: improved quality of life

Chronic wounds impair patients' quality of life considerably with respect to pain and general mobility. Chronic wounds often lead to social isolation and financial problems.15 Studies16 have shown that hydro-active dressings have no serious side effects even when used over long periods of time. Furthermore, the change of dressings causes hardly any pain and therefore results in improved patient compliance. The improved comfort associated with modern wound care dressings and the significantly shorter duration of treatment have positive effects on patient mobility.17

6.2.4.3 The economic aspects of modern wound care management

A number of studies document the economic aspects of modern wound care products.18, 19, 20, 21 All of these studies come to the conclusion that modern wound management with hydro-active dressings is cost-effective. Despite the higher unit prices of modern wound care products compared to the conventional dry dressings, the total costs of modern wound management are significantly lower than the traditional wound care products. Compared to conventional wound care, the studies show that modern wound care products are associated with

- less frequent changes of dressings,
- less time per change of dressing,
- a significantly reduction in the length of treatment.
A study of the German Association of Medical Device Manufacturers (BVMed) shows that modern wound care management can decrease total costs of treatment by 75 per cent. If the costs of painkillers and antibiotics had been included in the study, the economic advantages of modern wound care products would have been even greater.

Hospital utilization is reduced through shorter length of stay and reduced need for personnel. Dressings make up only about 0.5–0.6 per cent of total hospital costs; most costs in wound care are the costs of personnel (i.e. for the change of dressings). By using modern wound care products hospitals with high utilization rates thus benefit through reduced personnel costs and the shorter lengths of stay.

Office-based doctors benefit through the reduction in the time needed to treat patients with chronic wounds. Modern wound care methods have the potential to allow substantial savings in this sector due to the considerable decrease in the amount of time needed to dress and care for wounds. Furthermore, the prescription of expensive ointments is no longer necessary. The number of dressing changes drops dramatically.

According to estimates, the total annual savings potential in the treatment of chronic wounds on the basis of standard prevention measures and modern wound care techniques amounts to approximately 50 per cent of the present costs expended on the treatment of chronic wounds.

6.2.5 The reimbursement of modern wound care procedures and products

Wound dressings (both traditional and modern wound care products) are generally subject to coverage by the SHI funds, i.e. patients are entitled to treatment using these products. The SHI funds spend approximately 1.7 per cent of their expenditures in the ambulatory sector on wound dressings. Modern wound care products make up about 0.3 percent of total expenditures in the ambulatory sector.

In the ambulatory sector, traditional wound care products such as compresses, gauze, swabs and cotton are covered as part of general practice supplies. This is convenient for the physician, because the materials are invoice on a quarterly basis to the SHI funds. Since modern wound care products cannot be charged as general office supplies in a growing number of regions, physicians must order the products individually in the name of the patient.

The cumbersome process of prescription by the physician and the following procurement (e.g. in a pharmacy) by the patient as well as the additional co-payment of 8 DM hinder the use of modern wound care products.
Furthermore, the present reimbursement system for doctors' services does not differentiate between the traditional wound care products (with lower unit prices) and modern high-quality products (with higher unit prices). Since the physician's fees include material costs, it is "more profitable" for the physician to use the less expensive products. Defining a separate code in the fee schedule for the treatment of chronic wounds and modern wound care products could help to solve this problem.

In order to promote the improved and more efficient treatment of chronic wounds changes in the reimbursement system are necessary. Appropriate measures to this end include:

- admission of the modern wound care in all regional agreements on general practice supplies,
- a separate EBM code for the care of chronic wounds with modern wound care products,
- the abolition or a loosening of the budget restrictions on services associated with the treatment of chronic wounds.
6.3 Case study 2: Low energy pulsed ultrasound in the treatment of pseudoarthrosis

Each year there is an average of 650,000 bone fractures in Germany. The treatment of these injuries depends on the severity of the fracture: conservative treatment with a cast or brace and surgical procedures based on so-called osteosynthesis.

Usually, a fracture heals after this primary treatment. Only in a few cases, which constitute approximately 2 percent of the total number of the fractures, is the healing process retarded and/or stopped completely by other conditions or due to the general condition of the patient. In such cases, a patient is known to have pseudoarthrosis.

The conventional therapy for those 10,000 to 15,000 cases per year in Germany is surgical treatment based on osteosynthesis. However, for some years there has been a simple and minimally invasive alternative to surgical treatment of pseudoarthrosis: low-energy pulsed ultrasound therapy. This procedure is not only medically effective, it can also be used safely by the patient at home and is thus cost-saving.

While the advantages of this therapy have already benefited patients and have saved payers money in countries like the USA, Japan and the Netherlands for some years, persons insured under Germany's SHI system may not be treated using this therapy.

6.3.1 Bone fractures and pseudoarthrosis

The medical treatment of bone fractures differs according to the type and severity of the fracture: conservative treatment is based on plaster casts or braces while surgical treatment is based on so-called osteosynthesis, i.e. with plates, nails, screws etc.

Following the initial treatment, fractures usually heal easily and the bones grow together again. Depending on the type of fracture and other injuries, a fracture should heal within 3 to 4 months. Fractures that persist longer than this time period are referred to as delayed healing fractures. In a few cases the healing process stops completely. In such cases one speaks of a pseudoarthrosis.

6.3.2 Epidemiology of pseudoarthrosis

According to the Federal Statistical Office, there is an average of 650,000 fractures in Germany each year. In nearly all cases, bone fractures heal after initial treatment. The fractured bone does not heal by natural means only in approximately 2 per cent of the cases.

6.3.3 Standard treatment of non-healing fractures

The conventional therapy for the 10,000 to 15,000 cases of pseudoarthrosis each year in Germany is surgical osteosynthesis, which is usually performed as a dual procedure. First, the surgeon opens the point at which the fracture is located place and removes the cartilage that has grown into the fracture. Then this opening is covered and a new incision is made in the area of
the pelvis. The pelvis is the largest bone in the human body and can provide the most bone material.

The surgeon removes a piece of bone from the pelvis. This piece of bone is pulverized in a special grinder. The bone powder is then introduced into the bone fracture and the opening is closed. Following this, the incision in the pelvic area is closed.

This surgical procedure is associated with substantial risks. One of 1.000 operated patients do not survive anesthesia and there is the additional risk of infection. Furthermore, the two operations are very painful for patients.

After the operation patients must remain in the hospital for approximately two weeks and can not work for another 6 weeks. According to a literature search of the entire English and German literature published between 1975 and 1996, the success rate of surgical osteosynthesis is approximately 85 per cent.

### 6.3.4 Ultrasound therapy for the treatment of non-healing fractures: a minimally invasive alternative to osteosynthesis

Low energy pulsed ultrasound therapy, which can heal pseudoarthrosis without surgical intervention, is an alternative to the above-mentioned procedure in the treatment of pseudoarthrosis.

Patients are taught how to use the device by the doctor and can take it home with them, where they use it for approximately 20 minutes each day. Depending on the severity of the case, the total treatment lasts between 120 and 160 days (i.e. roughly as long as the recuperation and healing period following osteosynthesis).

### 6.3.5 How low-energy pulsed ultrasound functions

Low-energy ultrasound has been used to heal bone fractures since 1983. Ultrasound is an acoustic signal that generates a micromechanical pressure and micromechanical energy that affects bones and the surrounding tissue.

In contrast to other uses of ultrasound in medical treatment (e.g. in surgery and physical therapy), where the effect is attained through heating the exposed tissue, low-energy ultrasound operates at very low energy levels. Thus, the amount of energy given off by a low-energy pulsed ultrasound device are roughly equal to the energy levels of diagnostic ultrasound and pose no risk to patients.
Clinical studies on cells that were conducted at the Mayo Clinic revealed that the calcium channels of individual cells open rapidly when exposed to this type of ultrasound. This increases the inflow of calcium five-fold and thus promotes the formation of massive bone.

In a study of 40 patients by Gebauer et al the average duration of therapy was 142 days. Of the 40 patients in the study, the treatment was successful in 36 cases. Mayr reported a success rate of approximately 90 per cent in a group of 120 patients.

All patients were spared the need for a hospital stay, surgery and follow-up care. All patients could pursue their normal activities during the course of treatment. These studies on the efficacy of the procedure were validated by biometric and legal expertises.

This evidence indicates that the medical efficacy of low-energy ultrasound therapy is at least equal to or greater than the success rates for surgical osteosynthesis.

6.3.6 The economic aspects of low-energy pulsed ultrasound therapy in the treatment of pseudoarthrosis

Economic analyses of low-energy ultrasound therapy indicate that the treatment of non-healing fractures with this procedure is associated with much lower costs than the traditional surgical procedures.

According to the 1996 statistics of the general health insurance funds, surgical osteosynthesis cost 12,000 DM on average, including sick pay. The total costs per case for other health insurance funds is probably more, since the sick pay for the salaried workers insured by these funds is usually higher than that for the workers insured under the general funds.

Pseudoarthrosis therapy with low-energy ultrasound costs the health insurance funds only 6,000 DM. These costs include the rental of the device, instructing the patient how to use the device, a hotline in case patients need assistance, the costs of physician treatment, x-rays, etc.

According to an economic study of pseudoarthrosis treatment in Germany, the costs per case of low-energy ultrasound therapy are approximately 2,600 DM lower than the costs of surgical treatment. These costs include the costs of sick pay but do not reflect all hospital costs (since the hospital rates cover only operating costs). If capital costs in the hospital sector are included, the cost advantage of low-energy ultrasound therapy is close to 7,000 DM per case.

From the societal perspective, the study concludes that the total annual savings to the SHI system would be 51.2 million DM if all hospital costs are included and 14.3 million DM if only the operating costs of the hospital sector are used.
An economic study of the procedure in Austria revealed similar a savings potential compared to surgical techniques.  

### 6.3.7 The reimbursement of low-energy pulsed ultrasound therapy in the SHI system

Social security institutions and private third-party payers in other countries have recognized the medical and economic advantages of the low-energy ultrasound therapy for the treatment of pseudoarthrosis. The therapy has been used for years in the USA and is covered as an insurance benefit.

In Japan, low-energy ultrasound therapy has been accepted by the Ministry of Health Koseibo as a reimbursable benefit for the treatment of non-healing fractures. In the Netherlands the Ziekenfondsraad has the recognized low-energy ultrasound therapy for the treatment of fractures "that have not healed for 6 months and for which the therapy can help to avoid a (further) operation ".

In Germany, on the other hand, SHI patients cannot profit from the advantages of the low-energy ultrasound therapy, because the federal committee of doctors and SHI funds did not recognize the medical and economic use of this therapy. This committee is responsible for determining whether a procedure can be reimbursed under the social health insurance system.

According to the social legislation, products like the low-energy ultrasound device - which is to classified as an aid – must first be reviewed with respect to medical necessity and efficiency by the health insurance funds (usually by the medical advisory service of the health insurance companies, the MDK) and by the federal committee of the doctors and SHI funds.

In the case of the low-energy ultrasound device, the leading manufacturer submitted an application for coverage of the device on November 22, 1996 "for the healing of pseudoarthrosis and delayed fracture healing".

The review and investigation of the low-energy ultrasound therapy device took nearly 1.5 years, i.e. from November 1996 to at the end of January 1998.

In April 1998, the committee announced that low-energy ultrasound therapy is not to be covered by the SHI funds as a treatment. A detailed explanation of the decision of the federal committee must not be provided and was not given; the decision-making process and the grounds for the actual decision are therefore unknown. As result of the negative decision of the federal committee, SHI funds may not cover this form of treatment for pseudoarthrosis. Furthermore, the SHI funds cannot take advantage of a rebate warranty for unsuccessful application that is
offered worldwide by the manufacturer. From the patient perspective the only way out of this dilemma is self-payment.

The process and the results of the federal committee's decision-making exemplify the need for quicker and above all more transparent structures in the German healthcare system's "self-management". 
6.4 Case study 3: Hyaluronic acid in the treatment of osteoarthritis of the knee

The term "osteoarthritis of the knee" designates all degenerative diseases of the knee that are characterized by the progressive, mechanical wear of the joint cartilage as well as the connective and supporting tissues of the knee joint.

The number of patients with arthritis in Germany is estimated at approximately 5 million (6% of the population), of which a large number suffer from osteoarthritis of the knee.

According to the guidelines of the German Society for Orthopedics and Traumatology and the Association of Orthopedic Surgeons for treating osteoarthritis of the knee, visco-supplementation with hyaluronic acid preparations is among the therapy options.

Since the medicine product law took effect in 1995, some hyaluronic acid products are no longer classified as pharmaceuticals but as medical devices. This change in the legal basis for the classification of the products has bad consequences, because medical devices generally do not fall under the explicit coverage of the SHI funds. Therefore, the costs of the products classified as medical devices are not covered by the SHI funds, while the cost of the products classified as pharmaceuticals are covered in full (less a small prescription fee).

6.4.1 Diseases of the knee joint: osteoarthritis

The term osteoarthritis of the knee denotes all degenerative illnesses of the knee joint, which are characterized by the progressive, mechanical wear of the joint cartilage as well as the binding and connective tissue in the knee joint. Due to pathological change in cartilage and in the joint, the bones and the joint capsule are affected.

Physicians distinguish primary from secondary osteoarthritis of the knee. Primary arthritis is relatively rare and its causes unknown, but probably lie in an innate weakness of the cartilage tissue.

The causes of the secondary osteoarthritis of the knee are well known and numerous: e.g. wrong position of the leg axle, overloading, injuries of the knee joint, and metabolic or endocrinary diseases. The condition is also affected by factors such as obesity and false posture.

Patients with osteoarthritis of the knee frequently complain about joint pain and limited mobility. "Morning warm-up pain" is typical for osteoarthritis of the knee: after rising, pain exists in the knee joint, but fades after a short walking distance. The pain can also be accompanied by stiffness, which rarely lasts longer than 30 minutes.

After long walks, particularly on uneven terrain, so-called fatigue pain can arise. Pain may also occur after exertion. The occurrence of all three kinds of pain, - warm-up, fatigue, and exertion - is considered as a sure sign of osteoarthritis.28
6.4.2 Epidemiology and socioeconomic data on osteoarthritis of the knee

No data is available for Germany on the number of the patients with osteoarthritis and in particular with osteoarthritis of the knee joint. The number of the patients with arthritis-related complaints in Germany is estimated at approximately 5 million (6 % of the population). According to data on the prevalence of osteoarthritis (which is based on data from the Netherlands) published in the Health Report for Germany 29, osteoarthritis of the knee is the third most common form of osteoarthritis (following osteoarthritis of the fingers and wrists). Other sources estimate the prevalence of osteoarthritis of the knee in the population over 60 years of age at between 27 and 90 per cent.

Since the prevalence of the osteoarthritis as degenerative joint disease is strongly correlated with age, the health report predicts a pronounced increase in the number of the patients with osteoarthritis over the next years. By the year 2010, one out of five individuals could be affected; i.e. the number of the patients with osteoarthritis could rise to over 16 million.

In 1995, over 6 per cent of all disability pensions, nearly 8 million sick days and 4.4 million hospital days were attributed to osteoarthritis.

6.4.3 Treatment options

The German Society for Orthopedics and Traumatology and the Association of Orthopedic Surgeons have published general guidelines for the treatment of osteoarthritis of the knee.

Since there is no cure for osteoarthritis, the therapies recommended in the guidelines aim at relieving pain, improving the quality of life, increasing mobility and delaying the progression of the disease. The guidelines also provide an overview of the therapy options.

Furthermore, the guidelines recommend treatment alternatives on the basis of the stage of a patient's condition. Indicators for the choice of therapy include pain, the extent of the arthritis, therapy resistance, the age of a patient, deformity, mobility, discomfort and co-morbidity.

- For stage 1 the guidelines recommend ambulatory treatment with counseling, physical therapy, knee training (muscle training and behavioral change), analgesic and/or antiphlobistic pharmaceuticals and local injection therapy. Commonly used pharmaceuticals are the so-called non-steroid antirheumatics (NSAR), although these often have serious side effects. Local injection therapy includes local anesthesia and the injection of so-called "symptomatic slow acting drugs in ostearthritis" (SYSDOA). The local injection of SYSDOA is intended to replace or replenish the synovial fluid in the affected joint and thus relieve the symptoms of osteoarthritis and slow the progression of the disease. However, the
term "drug" is misleading in this context, since not all of the products that fall under this term are considered to be pharmaceuticals. As discussed below, this fact has resulted in problems for the reimbursement of these products.

- In stage 2 the guidelines recommend arthroscopy on an inpatient or outpatient basis. Arthroscopy includes procedures such as debridement and lavage, i.e. the removal of damaged tissue and rinsing the synovial area of the knee. Although arthroscopy is used primarily for diagnostic purposes, patients with osteoarthritis often experience relief from their symptoms following arthroscopy. As a result, arthroscopy is used increasingly for therapeutic as well as diagnostic purposes.

Arthroscopy is not usually associated with complications and therefore preferable to the surgical measures described below. The infection rates are very low and there are very low mortality rates associated with the procedure. In the case of osteoarthritis of the knee, the greatest risk is that the procedure is performed too aggressively, which can lead to an increase in pain.

Debridement and lavage has good results in 60-80 per cent of the patients with moderate symptoms. Within four years, however, close to 50 per cent of all patients have the same symptoms as before the procedure. The success rate decreases after repeated interventions, and once this option is exhausted, there are few alternatives other than the total knee replacement. As a result, the postponement of arthroscopic treatment of osteoarthritis can have definite advantages for patients.

- In stage 3, the guidelines recommend osteotomy in the area of the joint. Since this procedure can only be performed in certain patients, total knee replacement is the typical surgical treatment in later stages of the disease.

- In stage 4, the guidelines recommend total knee replacement. This final stage of osteoarthritis of the knee is defined as the stage in which pharmaceutical therapy and arthroscopy bring about no pain relief and the only remaining options are open surgical procedures.

As an extremely invasive and costly procedure, total knee replacement is often delayed until a patient is over 60 years of age. This is also due to the limited service life of artificial joints and the poor success rates of repeat surgery.

There is thus a considerable need for treatment methods such as visco-supplementation with hyaluronic acid to ease the symptoms in patients, especially those in later stages of the disease, and to postpone the necessity of total knee replacement for as long as possible.
6.4.4 Injection therapy with hyaluronic acid: Data on efficacy, quality of life and cost-effectiveness

Hyaluronic acid is found in many parts of the human body: in the eyes, the skin, cartilage and in the so-called synovial fluid. Synovial fluid is a clear, liquid secretion that is produced in the joints and which protects the joints with its unique lubricating and shock absorbing characteristics.

In patients with osteoarthritis, less hyaluronic acid is present in the joints. Furthermore, that which remains is often less elastic and can not fulfill its function as a lubricant and cushion.

The efficacy and effectiveness of hyaluronic acid injection therapy has been analyzed in various randomized double-blind studies and was found to have a positive effect on symptoms and joint function. Compared to NSAIRs and steroids, the visco-supplementation was shown to have equal or better effects. The studies also reveal that the rate of side effects of hyaluronic acid is comparable to those of the placebo.

The results of a German study of the cost-effectiveness of hyaluronic acid and its effects on the quality of life underscore the advantages of visco-supplementation with a hyaluronic acid preparation.\(^\text{30}\)

Although the direct costs of hyaluronic acid treatment are greater than those of the standard treatment, these costs were more than offset by savings in the area of additional therapies and sick pay.\(^\text{31}\) In term of quality of life (e.g. mobility, pain, overall condition), the injection therapy with a hyaluronic acid-based product was superior to NSAR therapy. The authors of the German study conclude that treatment with a hyaluronic acid-based product "does not result in higher costs, and contributes to reducing the costs of pharmaceuticals with many side effects and improves quality of life."\(^\text{32}\)

6.4.5 The reimbursement of hyaluronic acid products for the treatment of osteoarthritis in Germany

Hyaluronic acid preparations for the treatment of osteoarthritis represent a special case in Germany in so far as they were formerly registered as pharmaceuticals but now can be sold as medical devices. Originally, all hyaluronic acid preparations were registered as "quasi pharmaceuticals" (Geltungsarzneimittel) according to par. 2 of the German Drug Law. They were prescribed and reimbursed as pharmaceuticals and thus subject to the regulations on the pharmaceutical budget.
Since implementation of the Medical Device Law in 1995 hyaluronic acid preparations for the treatment of osteoarthritis may be marketed as medical devices. However, these products fall into a gray area of regulatory and social insurance provisions.

The classification of the product is up to the manufacturer. The rule of thumb for classification purposes – which has been confirmed by a working group of the European Commission - is that medical devices work by physical means while the primary effect of a pharmaceutical is produced by pharmacological means.

In the Rote Liste, the drug compendium of the Germany's leading pharmaceutical associations, the differences in the regulatory status of the hyaluronic acid preparations for the treatment of osteoarthritis are obvious. The chapter "Analgesics/Antirheumatics" lists three such products for the treatment of osteoarthritis. Two of the products are prescription only while the third can be bought over the counter and is not restricted to pharmacies. Another hyaluronic acid preparation is listed in the chapter "Biomaterials/Medical plastics/Diverse" as the sole listing in the section "Diverse". This product is also a medical device and is subject neither to prescription regulations nor to pharmacy-only sale.

These differences in the classification of the various products has considerable implications for manufacturers, since the social insurance regulations only require SHI funds to cover pharmaceuticals, dressings and handicap aids. This means that the costs of those preparations that are registered as pharmaceuticals are covered in principle by the SHI funds while the costs of those that are marketed as medical devices must not be reimbursed.

A notice sent by some national SHI associations to their member funds informs them not to cover the costs of hyaluronic acid products that are marketed as medical devices. The German Ministry of Health, however, recommended that products that formerly fell under the German Drug Law and are now listed as medical devices are still covered by social insurance regulations. A solution to this unequal treatment has not yet been found. The costs of the hyaluronic acid preparation that is marketed as a pharmaceutical are still covered by the SHI funds (although they are subject to the tight restrictions of the Pharmaceutical Guidelines of the National Committee of Doctors and SHI funds), while patients must carry the full costs of those products that are marketed as medical devices.
6.5 Case study 4: Uterus balloon therapy

The present surgical treatment of therapy-resistant dysfunctional uterine bleeding (DUB) in Germany is based on hysterectomy and endometrium ablation. Uterus balloon therapy represents a refinement of the "classical" methods for endometrium ablation (i.e. laser, loop and roller-ball).

As a minimally invasive procedure, uterus balloon therapy benefits patients as well as payers through a reduction in hospital length of stay, speedier recovery and reduced sick leave. However, the present system of hospital remuneration does not "reward" these benefits. Hospitals have few incentives to use minimally invasive procedures because they are often paid for them on the basis of per diems.

Uterus balloon therapy has been on the priority list of the committee "Medical Treatment" since September 1999.

6.5.1 Dysfunctional uterine bleeding: Epidemiological data

Dysfunctional uterine bleeding is classified as a type of menorrhagia, a concept that covers all types of strong menstruation. DUB is defined as extreme menstruation (longer than 7 days or more than 80 ml.) that is due neither to a specific condition, e.g. polyps and myoma or cancerous growths, nor to complications during pregnancy. DUB can affect all females between puberty and menopause.

Roughly one fifth of otherwise healthy females are affected by menorrhagia. Of those, 30 per cent suffer from DUB. The large loss of blood is usually perceived as extremely bothersome. Patients often find it difficult to go about their normal daily affairs during menstruation. In extreme cases, menorrhagia poses a hazard to a patients' general health, is an extreme psychological burden and can lead to social isolation. Treatment options in such cases include the therapies described in the following sections.

6.5.2 Treatment options for DUB

The following options exist for the treatment of DUB:

- pharmaceutical therapy
- hysterectomy (surgical removal of the uterus)
- different methods of endometrium ablation, including roller-ball, loop and laser ablation
- uterus balloon therapy
6.5.2.1 Pharmaceutical therapy

Hormone therapy with gestagens can prevent the development of more serious hyperplasia or endometrium cancer and lead to a shrinking of the endometrium. The efficacy of current pharmaceutical therapies ranges between 20 and almost 100 per cent. However, pharmaceutical therapy is often unsuccessful or results only in short-term success. In addition to the often-serious side effects, this form of treatment requires continued application in order to reduce the loss of blood.

6.5.2.2 Hysterectomy

Hysterectomy is considered the standard surgical treatment of DUB in Germany and is performed on some 150,000 patients each year. The removal of the uterus is often a great physical and psychological burden for patients.

This procedure is also associated with long-term side effects; e.g. earlier onset of menopause by 5 years, and increased risk of incontinence. Hysterectomies are performed in a hospital setting, require 7-12 days of hospital stay and 6 weeks sick leave.

6.5.2.3 Hysteroscopic endometrium ablation

Endometrium ablation was first described 15 years ago. Today the procedure is usually performed with a ND:YAG laser, electric loops or a "roller-ball". Following diagnosis (histology, diagnostic hysteroscopy), hormone treatment with costly GnRH therapy is necessary to cause the endometrium to shrink before the procedure can be performed. Die success rate for experienced surgeons is more than 90 per cent. However, serious complications are not unknown. Comparisons of the various procedures have been made by Gallinat, Gallinat et al., Meyer und Wamsteker et al.

6.5.3 Uterus balloon therapy: Data on efficacy, quality of life and efficiency

Minimally invasive uterus balloon therapy can be performed as day case surgery in the hospital or in the clinics of office-based doctors. On average, the procedure takes 20.3 minutes and patients are discharged from the hospital within 24 hours. The advantages of the therapy lie primarily in its high success rate, the short time in surgery, the minimal complication rate and the improved quality of life for the patients. Sick leave following the procedure is usually no longer than 5 days.
6.5.3.1 Efficacy

Success rates are as high as 95 per cent, depending on the type of device used. Multi-center studies by Amso et al.\textsuperscript{40} and Meyer et al.\textsuperscript{41} show that a marked improvement is experienced by 80-90 per cent of all patients. According to multi-center studies of Soderstrom et al.\textsuperscript{42}, Dequesne et al.\textsuperscript{43} and Corson et al.\textsuperscript{44}, the success rates of the uterus balloon therapy are equal to or better than those for laser and roller-ball treatment and at considerably lower complication rates. In a study conducted by Cooper\textsuperscript{45}, electrothermal endometrium ablation was shown to be more effective than pharmaceutical therapy.

6.5.3.2 Patient benefits: Improved quality of life

Uterus balloon therapy has a number of advantages over hysterectomy:

- shorter time in surgery
- shorter hospital length of stay
- fewer post-operative complications
- shorter recovery time

With respect to quality of life, the role of the uterus for the well being of a patient is decisive. Many women who are confronted by the prospect of having a hysterectomy fell anxious and depressed over the impending loss of the uterus. In almost all cases, the removal of the uterus is perceived as a major intervention that threatens the integrity and harmony of the organism.

6.5.3.3 Efficiency of the minimally invasive procedure

According to Gallinat\textsuperscript{46}, minimally invasive procedures such as endometrium ablation could reduce the necessity for a hysterectomy in up to 80 percent of selected patient groups.

Based on the costs of three procedures for the treatment of DUB, it is estimated that the SHI system would spend roughly 500 million DM less if 80 per cent of the hysterectomies performed in Germany were replaced by the uterus balloon procedure.\textsuperscript{47} This savings potential, which includes only the direct costs of treatment, result from the fact that a hysterectomy is paid for on the basis of a per-case hospital rate of approximately DM 6,200 while endometrium ablation or uterus balloon therapy costs only DM 2,300.

Hidlebaugh et al.\textsuperscript{48} report of considerable savings in direct and indirect costs of endometrium ablation compared to hysterectomy ($5,434 versus $8,417).
6.5.4 The reimbursement situation for uterus balloon therapy

6.5.4.1 Reimbursement in the hospital sector

Since there are no per-case payments or procedural rates for uterus balloon therapy, hospital payment for this procedure is based on a hospital's per diem rates. This often leads to the dilemma that the costs of a procedure can only be covered by extending the length of hospital stay - a strategy that obviously negates the philosophy underlying minimally invasive procedures.

A hysterectomy is paid for on the basis of a per-case payment (FP 15.02), which is valued at approximately DM 6,172. Given the average per diem rate of DM 412 for hospital gynecology departments (1997), a patient would have to be kept in a hospital for two to three days in order to cover only the material costs of the uterus balloon procedure. In order for a hospital to break even with the procedure, the patient must stay in the hospital for a number of days even though she could be treated and released in one day.

6.5.4.2 The ambulatory sector

Private health insurers are often more open to new procedures and usually cover the costs of uterus balloon therapy. However, patients covered by the SHI system have more trouble receiving approval for this procedure. There is no separate code on the doctors' fee schedule for endometrium ablation and uterus balloon therapy. In such cases, the SHI funds are not obliged to cover the costs of such procedures. As long as the National Committee of Doctors and SHI Funds have not made a negative decision on the procedure, the SHI funds have been willing to assume some or all of the costs of this procedure.

In such cases, the doctor must apply for approval to use the procedure to the patient's SHI fund and the expenditure is accounted as part of the doctor's practice budget (Praxisbudget). The tedious and time-consuming procedure of applying to SHI funds for prior approval is often a wasted effort for doctors and patients, since SHI funds increasingly deny approval to applications. For patients whose SHI funds refuse to cover the costs of these procedures, uterus balloon therapy must be paid for by the patients themselves.

In the future, day-case surgery will be increasingly reimbursed on the basis of flat rates. Until a nationwide fee schedule for day-case surgery has been implemented, the only alternative is to negotiate special regional rates for uterus balloon therapy.
6.6 Case study 6: PTCA and Stents in the Treatment of Coronary Artery Disease

Coronary heart disease is the most common cause of death in Germany. In 1997, approximately 179,000 people died of coronary artery disease. An estimated 46 percent of these deaths were due to heart attacks. Advances in medicine and medical technology have helped reduce the mortality due to heart attacks by 30 percent between 1980 and 1997.

Pharmaceutical therapy and behavioral changes (e.g., diet, exercise and stress reduction) are the primary forms of therapy in the early stages of coronary artery disease. In advanced stages, when the risk of a heart attack due to a narrowing of the coronary arteries is very high, the standard therapy until the end of the 1970s was coronary bypass surgery.

Since 1977, with the introduction of balloon angioplasty, it has been possible to treat many blockages in the coronary arteries using the less invasive procedure known as Percutaneous Transluminal Coronary Angioplasty (PTCA). This procedure involves the introduction of a balloon catheter into an artery in the groin. The catheter is guided through the circulatory system until it reaches the site of the blockage. The balloon is expanded in the artery, thereby increasing the lumen of the artery and increasing blood flow. This procedure was performed approximately 150,000 times in Germany during 1998.

While PTCA is a major advance in the treatment of coronary artery disease, it has two serious limitations; a 2-10% incidence of abrupt vessel closure and the need for repeat revascularization procedures in 30-50% of patients, because of renarrowing of the vessel.50

The introduction of stents in the early 1990's has virtually eliminated the incidence of abrupt vessel closure and the corresponding need for emergency coronary bypass surgery. Stents have also reduced the need for repeat interventions to between 9 and 14% for de novo lesions (this corresponds to a reduction of 33-65% as compared to balloon angioplasty).51

Studies have shown that the use of stents leads to an improvement in clinical outcomes and an efficient use of the health care budget for treating patients with coronary artery disease.52

The current procedural reimbursement schemes only apply to PTCA's and not to stent implantations. The absence of specific reimbursement for new technologies (e.g., for stenting) provides a disincentive for physicians to treat patients with these innovative products, which have been shown to be cost effective and improve clinical outcomes.

The introduction of breakthrough technologies and innovative, cost-effective medical products benefits patients, payers and the German health care system equally. However, adoption of these therapeutic advances in Germany requires the creation of a health care system, which will allow timely reimbursement of new medical technologies.

6.6.1 Coronary Artery Disease

The heart is a hollow muscular organ. It works like a pump and supplies the entire body with blood, oxygen and nutrients. A healthy heart ensures that the body is provided with fresh blood once every minute. In the course of one day, the heart pumps between 6,000 and 8,000 liters of blood.

In order to perform these tasks, the heart itself must also have an adequate supply of oxygen and nutrients. The supply of blood to the heart muscle itself is transported through a network of coronary arteries.
Coronary artery disease is a general term for processes that lead to a narrowing or blockage of the coronary arteries. Healthy coronary arteries are elastic and muscular, and can adapt to changes in blood pressure. Under some conditions, e.g., when the arterial walls are damaged, fatty deposits collect in the arteries. This process usually begins gradually and may involve different arteries. In the course of the disease, other substances, such as calcium, may infiltrate these deposits. The artery narrows and can obstruct the blood flow so that certain regions of the heart do not receive a sufficient blood supply.

While the precise causes of coronary artery disease are unclear, it is likely that some components are hereditary and factors such as smoking, high blood pressure and elevated cholesterol levels have been shown to increase the risk of coronary artery disease.

When coronary arteries become too narrowed or a blood clot forms, it may cause a total blockage of an artery, thereby leading to a heart attack. The lack of blood supply to the affected area of the heart leads to the death of the heart muscle tissue (myocardial infarction). This in turn weakens the heart's pumping capacity and can cause death or lead to other cardiac problems, such as heart rhythm disturbances.

### 6.6.2 Coronary Artery Disease and Myocardial Infarction: Epidemiological Data

There are approximately one million known cases of coronary artery disease in Germany. However, it is assumed that the number of unreported cases is considerably higher.

According to data from the German Statistics Office, coronary artery disease and myocardial infarction are the most common causes of death in Germany. In 1995, coronary artery disease caused 184,000 deaths, 88,000 of which were due to myocardial infarction, making it the leading cause of death in Germany.

It should be noted, however, that the mortality rate of myocardial infarction has declined considerably since the early 1980s. For men, the mortality rates declined by 40 percent between 1980 and 1995. The mortality rate among women, which is lower than that for men, dropped by 25 per cent during the same time period. This trend is primarily due to a reduction in mortality in the hospital setting. "These results demonstrate the importance of improved acute care facilities and advances in therapy in reducing the mortality due to heart and circulatory diseases."

### 6.6.3 Treatment of Coronary Artery Disease

The three primary means of medical treatment for coronary artery disease are:

- pharmacological therapy
• coronary bypass surgery
• percutaneous coronary interventions, such as Percutaneous Transluminal Coronary Angioplasty (PTCA) and stenting

6.6.3.1 Pharmacological Therapy

Depending on the patient's condition, physicians often use different drugs or combinations of drugs to treat ischemic heart disease. The most important pharmaceuticals are β-blockers, calcium antagonists and nitrates. According to the recommendations of the German League for Combating High Blood Pressure, these pharmaceuticals can be used alone or in combination with other anti-hypertension drugs. The reduction of blood pressure is necessary for preventing or alleviating further damage to the arteries.

More recently, many physicians also prescribe statin drugs to reduce the low-density lipoprotein (LDL) cholesterol. Clinical studies have shown that a reduction in LDL cholesterol can decrease the incidence of adverse cardiac events. Drugs for the treatment of hypertension and coronary artery disease are among the most sold pharmaceuticals in Germany. According to the “Arzneiverordnung” Report 1997, the Statutory Health Insurance (SHI) funds spent almost DM 7 billion on the above-mentioned drugs in 1996. This represents about 20 per cent of total pharmaceutical expenditures.

6.6.3.2 Coronary Bypass Surgery

Coronary bypass surgery is an invasive procedure in which diseased coronary arteries are bypassed or replaced with blood vessels from other parts of the body. Usually, a vein from the leg or internal mammary artery is used for this purpose. Most bypass operations are performed on a resting heart using a heart-lung bypass machine.

The heart-lung machine ensures that the patient's body is supplied with oxygenated blood during surgery and allows the surgeon to suture the vessels onto a heart that is not beating.

According to the "Herzbericht 1998", approximately 74,000 bypass procedures were performed to treat coronary artery disease in Germany's 79 heart centers in 1998; 55,000 male patients and 19,000 female patients. At an average cost of about DM 25,000 per procedure, the total cost of coronary artery surgery was approximately DM 1.9 billion. Adding the average rehabilitation costs of DM 4,500 per patient results in total costs of more than DM 2.2 billion per year.
6.6.3.3  Percutaneous Transluminal Coronary Angioplasty (PTCA) and Stents

PTCA, also known as balloon angioplasty, was introduced in 1977 as a non-surgical procedure for the treatment of coronary artery disease. In this procedure, a narrowed or blocked section of an artery (called a stenosis) is expanded by means of a balloon catheter.

According to the "Herzbericht 1998", 146,662 PTCAs were performed in Germany during 1998. Since the payment for a PTCA procedure differs considerably according to the sector in which it is performed, only a rough estimate of total expenditures is possible. Assuming that 83 percent of all PTCAs were performed in hospitals, the total spending on this procedure amounted to approximately DM 994 million. Since rehabilitation measures are necessary for only about 20 percent of PTCA patients, the total rehabilitation costs are relatively low (DM 132 million).

Since the introduction of PTCA in 1977, the techniques and patient management in coronary artery angioplasty have been further refined to improve clinical outcomes and reduce the need for repeat procedures and other adverse events.

A particularly important development has been the introduction of stents, which are small metal tubes that are inserted into diseased coronary arteries to increase the blood vessel's luminal diameter and to prevent vessel recoil or abrupt reclosure, and thereby to restore normal blood flow through the artery. The stent is delivered to the site of the diseased artery by means of a balloon catheter inserted through the skin into the femoral (groin) artery.

This breakthrough device has markedly increased the safety of angioplasty performed in cardiac patients and has led to dramatic reductions in emergency bypass surgeries.

Figure 6.1  Emergency coronary artery bypass graft surgery for failed percutaneous transluminal coronary angioplasty: changes with the evolution of coronary stenting.
6.6.4 PTCA and Stents: Efficacy and Cost-effectiveness of Procedures

6.6.4.1 Efficacy of PTCA

PTCA (balloon angioplasty) involves the introduction of a balloon catheter into an artery in the groin. The catheter is guided through the circulatory system until it reaches the site of the blockage. The balloon is expanded in the artery, thereby increasing the lumen of the artery and increasing blood flow. It was and continues to be used primarily for treating patients with single vessel disease, although it is also being used selectively to treat patients with multi-vessel disease.

While PTCA was a major advance in the treatment of coronary artery disease it had two serious limitations; a 2-10 per cent incidence of abrupt vessel closure and the need for repeat revascularization procedures in 30-50 per cent of patients.

6.6.4.2 Efficacy of Stenting

Stents were originally developed to treat threatened and acute vessel closure, to reduce the incidence of restenosis (renarrowing of the vessel) and the need for repeat revascularization procedures. The introduction of stents in the early 1990’s has virtually eliminated the incidence of abrupt vessel closure and the corresponding need for emergency coronary bypass surgery. Stents have also reduced the need for repeat interventions by 33-65 per cent.

In addition, they have made PTCA much safer to perform. The clinical value of stents has clearly been demonstrated by a reduction in acute complications and need for emergency bypass surgery. The clinical evidence and experience indicates that stents are the treatment of choice for either acute or threatened closure complicating PTCA and for the treatment of dissections.

Stents have also reduced the need for expensive repeat interventions to between 9 and 14 percent for de novo lesions (a reduction of 33-65% as compared to balloon angioplasty).and similar reductions have been demonstrated in patients with re-narrowed lesions and total occlusions.

When considering all of the indications for stenting (e.g., de novo -first time- lesions, total chronic occlusions, restenotic lesions, acute myocardial infarctions and multi-vessel disease) physicians are currently using stents in 60-80 per cent of all percutaneous interventions. The superior clinical outcomes and cost-effectiveness of coronary stenting justify these high usage rates.
6.6.4.3 Cost-effectiveness of PTCA and Stents

A PTCA procedure in a German hospital costs only about one-fourth the price of coronary bypass surgery. A comparison of the costs of PTCA, PTCA with stents and bypass operations for the treatment of patients with single-vessel disease in German hospitals revealed that PTCA with stents cost less per patient than PTCA alone in the long run, even though the initial costs of the combined PTCA and stenting procedure are about 10 per cent greater than the costs of a PTCA alone.\(^{63}\)

Overall, the average treatment costs of patients treated with a stent are about 6.3 percent lower than the costs of PTCA alone after three years.

Numerous other prospective, randomized clinical studies have shown that the use of stents leads to a significant improvement in clinical outcomes and an efficient use of limited health care resources in the treatment of patients with coronary artery disease. Thereby, improving patient quality of care and achieving a benefit for society.\(^{64}\)

6.6.5 Reimbursement of PTCA and Stents

In the hospital sector, PTCAs are paid for on the basis of a procedural rate (Sonderentgelt SE 20.02) that is valued at approximately DM 6800. In addition, a hospital receives a per diem payment for each day of hospital stay, which means that the total reimbursement of a PTCA in the hospital sector amounts to approximately DM 8470.- (average length of hospital stay 3 days).

Since April 1, 1999, the total material costs associated with PTCAs (catheters, stent implants, contrast media, wound closure material etc.) performed in the office-based sector amounts to DM 2,070.-/ DM 3,420.- (single-vessel/multi-vessel PTCA). In addition to this, the physician receives his fee, which is approximately DM 1,170.

The current procedural reimbursement schemes only apply to PTCAs and not to stent implantations. The absence of specific reimbursement for new technologies (e.g. for stents) provides a disincentive for physicians to treat patients with innovative products that have been shown to be cost effective and improve clinical outcome.

In addition, the reimbursement system for the office-based sector should be designed to ensure that all cost-effective procedures that can be safely performed in this sector are adequately funded. Unfortunately, the low reimbursement rates for PTCA and stent procedures limit the number of cases that will be performed in the office-based sector.

In conclusion, major medical advances and cost-effective medical technologies, such as stenting, benefit patients, payers and the German health care system equally. However,
adoption of these therapeutic advances in Germany requires the creation of a health care system, which will allow timely and appropriate reimbursement, dedicated to the medical breakthrough technologies.
6.7 Case study 6: Progress in avoiding sudden cardiac death using implantable defibrillators

Irregular heartbeats, either in the form of disturbances of the time sequence of the heart beat or in the form of a heart beat that is too fast or too slow, can have several causes and different consequences of various severity for those concerned – including sudden cardiac death. In Germany, it is estimated that 100,000 patients per year die of sudden cardiac death, which is typically caused by ventricular tachycardia (VT) or ventricular fibrillation (VF). Although the risk to die of sudden cardiac death is highest in patients who have already experienced a severe arrhythmic event, most deaths occur in people who have not yet suffered such a life-threatening episode.

In arrhythmia patients with VT/VF, the conventional treatment is based on drug therapy, which often has considerable side effects and only poor long-term success rates. In patients who survived a severe heart rhythm disturbance, the cost effectiveness of implantable cardioverter defibrillators (ICDs) has been substantiated in several large, randomized clinical studies. The ICD is a device, which detects and treats abnormally fast heart rhythms. By delivering electric shocks, the device ensures that the normal heart rhythm is restored.

Advances in medical technology have made it possible to identify patient groups with a high risk of life-threatening cardiac rhythm disturbances and treat them. Even in high-risk patients in whom spontaneous VT/VF arrhythmia episodes have not yet occurred, ICD therapy has been proven to be a very effective means of prevention. This was demonstrated in prospective randomized multicenter studies.

In Germany, the effective and cost-efficient use of ICDs for primary prevention in high-risk patients is currently not commonly performed because of limited budgets.

6.7.1 Cardiac arrhythmias

The heart of a healthy adult beats between 60 and 100 times per minute. The heart beats because it generates electrical pulses that originate in an area of the heart called the sinus node. From the sinus node the electrical pulses travel through the heart muscle and stimulate the different areas of the heart in a way that the chambers of the heart are filled with blood from the body and then contract to pump the received blood back into the circulation. Disturbances of the electrical conduction system of the heart and other factors lead to an irregular heartbeat that is called arrhythmia.

There are different kinds of arrhythmias. Some are caused by disturbances of the electrical pulses in different areas of the heart and lead to a heartbeat that is too fast or too slow. The triggers of cardiac rhythm disturbances can vary considerably between individuals. Typical causes are lack of minerals, circulatory disturbances in the coronary arteries, inflammation of the myocardium, heart valve defects or scarring of the myocardium. If the heartbeat is too slow – which is called a bradycardia – the electrical pulses are delayed in reaching the ventricle. The first cardiac pacemaker was implanted in 1958 to treat this kind of arrhythmia.
If the electrical pulses of the heart do not originate in the sinus node but in the area of a ventricle, the heart rate will become too fast. This type of arrhythmia is called ventricular tachycardia or VT. Because the heart beats faster and faster, increasingly less blood is pumped through the circulatory system. If these rapid heartbeats continue, the brain and body cannot be supplied with sufficient blood and oxygen and unconsciousness or, in the worst case, cardiac arrest may occur. During ventricular fibrillation (VF), which often occurs in a heart muscle that is already damaged (e.g. as the result of myocardial infarction), the heart sometimes beats more than 300 times per minute, and several sites in the ventricles signal in an uncoordinated fashion how the heart is supposed to beat. With this type of arrhythmia, circulatory arrest with loss of consciousness or sudden cardiac death may occur within a few seconds.

The efficacy of ICDs as a means to prevent sudden cardiac arrest was demonstrated in the 1980s. However, pharmaceutical therapy remained the standard form of treatment for ventricular tachycardia and ventricular fibrillation well into the 1990s. However, advances in medical technology have made it possible to control such cardiac arrhythmia by better and less invasive means so that the implantation of an automatic defibrillator is now accepted as the standard therapy for certain indications. Modern ICDs monitor and control the heart continuously and automatically.

6.7.2 Epidemiological data on heart rhythm disturbances and sudden cardiac death

Precise data on the number of patients in Germany with cardiac rhythm disturbances is not available. Cardiac rhythm disturbances are among the 20 most frequent main diagnoses among patients treated in hospitals. According to the diagnostic statistics for hospitals of the Statistisches Bundesamt, approx. 242,000 patients were discharged from hospitals after treatment of cardiac rhythm disturbances in 1997. Of this group, 33,105 patients underwent surgery. Approximately 21,000 additional patients were discharged from hospitals because of "disturbances of the conduction system of the heart"; 9,140 of these patients had surgery in the hospital. It must be noted that these figures do not reflect the full scope of the problem.

According to the cause of death statistics of the German Statistics Bureau 12,818 deaths (5,561 males and 7,257 females) were caused by "disturbances in the conduction system of the heart and cardiac rhythm disturbances" in 1996. If one takes into consideration that cardiac rhythm disturbances also play a part in myocardial infarction and stroke, the deaths of a considerable percentage of those patients who died from acute myocardial infarction (85,206 in 1996) were probably due to cardiac rhythm disturbances. Unofficial sources estimate that as many as 100,000 deaths per year are caused by sudden cardiac death in Germany.65
6.7.3 Therapy options for sudden cardiac death

The primary objective of antiarrhythmic therapy is to prevent sudden cardiac death. 75 percent of all patients concerned die during the first VT/VF episode, which occurs, 25 percent survive, often with permanent damage. This is an important argument in favor of the use of ICDs in high-risk patients as a means of primary prevention (i.e. the implantation of an ICD before the first life-threatening episode occurs).

Drug therapy with so-called antiarrhythmic drugs typically forms the primary therapeutical approach in the treatment of cardiac rhythm disturbances. However, the drugs used often have severe adverse effects and only low long-term success rates.

The non-pharmaceutical treatment alternatives include catheter ablation and the implantation of automatic implantable defibrillators. External cardioversion is used primarily in emergency cases.

- In emergencies, if applied in a timely fashion, external cardioversion can be an effective means to restore the normal heart rhythm. During this procedure, electrical pulses are delivered to the heart from outside the body in order to restore the normal heart rhythm.

- During ablation therapy, the targeted delivery of radio-frequency current via a cardiac catheter is used to treat that part of the heart muscle, which is responsible for the cardiac rhythm disturbance so that electrical conduction will no longer occur in this area. The success rates of this procedure vary considerably depending on the area where the arrhythmia originates. Depending on the underlying cardiac disease the success rate in the treatment of ventricular tachycardias is between 50 and 90 percent.

- Progress in medicine and technology made it possible during recent years to refine the devices for cardioversion more and more and, above all, to make them small enough so that they can be implanted in the human body. The first of these devices was implanted in 1980. In Germany, where implantable cardioverter defibrillators (ICD) have been in use since 1984, ICDs are implanted in more than 5,000 patients receive each year.

6.7.4 Description of ICD systems and the way they work

An ICD system typically consists of an implanted pulse generator and one or more leads. The system monitors the electrical function of the heart and delivers electrical energy directly to the heart if an arrhythmia is detected that requires treatment.

ICD devices are implanted under the skin in the area of the clavicle. In order to deliver the electrical pulse, the ICD has an electrode, which is inserted in the right ventricle and another
electrode to monitor the heart rate. With some defibrillators, a third lead is placed in the right atrium in order to be able to detect what kind of rhythm disturbance occurs and to possibly deliver electrical pulses to the atrium.

Due to the continuing development of ICD devices and cardiological surgical procedures it is now possible to implant devices for the treatment of cardiac arrhythmias with less invasive methods and therefore reduce the risks of the surgical procedure. The implant of most modern ICD devices, which can be implanted without opening the thorax (thoracotomy), is associated with very low mortality rates (0.5%-0.8%).

6.7.5 Data on the efficiency and cost-effectiveness of this approach

Since their introduction about 15 years ago more than 200,000 ICDs have been implanted worldwide. The efficacy and cost-effectiveness of ICD devices for the treatment of ventricular arrhythmias was documented in many prospective and randomized trials. Patients who benefited from the ICD therapy were not only those with sustained ventricular tachycardias who had already survived a cardiac arrest (see e.g. CASH and AVID trials), but also selected patients at risk in whom a life-threatening arrhythmia event had not yet been documented (MADIT or MUSTT study, respectively) and where the ICD implant was for primary prevention.

The German "CASH Study" (Cardiac Arrest Study Hamburg), the first prospective trial to compare the ICD and antiarrhythmic drugs, demonstrated a statistically significant superiority of ICD therapy: The total mortality for ICD therapy was 37 percent lower than for drug therapy and the relative risk reduction was 85 percent.

Because of the relatively high direct costs of the ICD therapy – i.e. the costs of the hospital treatment and the implant – the cost-effectiveness of this type of therapy has received a lot of attention. The comparison of the cost-effectiveness of ICD therapy with that of standard therapies leads to surprising results in favor of ICD therapy. The first prospective and randomized study on cost-effectiveness of ICD therapy was initiated in the Netherlands in 1989 with the purpose of creating a basis for decisions on the reimbursability of this type of therapy.

Although the ICD devices tested in this trial were from an earlier generation (i.e. they had a lower longevity than modern devices and had to be implanted using an invasive surgical procedure), this study showed that ICD therapy is cost-effective.

In regard to the costs per additional year of life (cost per life year saved), the ICD therapy was found to be superior to the standard drug therapy at the time. A central conclusion of this study was: "The cost-effectiveness ratio... was $63 or $94, respectively, per patient per day in the ICD..."
and drug therapy groups …with a net cost advantage of $11,300 per patient per additional year of life."

The ICD group also had a higher quality of life than those patients treated with antiarrhythmic drugs since the latter suffered from arrhythmias more frequently, had a lower exercise tolerance, required more frequent and longer hospitalizations and had to change therapy more frequently.

Another comparative analysis of ICDs and drug therapy is the MADIT cost-effectiveness trial\(^9\) in which the costs in more than 300 patients were assessed. The main result of this cost-effectiveness study reflects the results of the central MADIT trial: Patients with ICD therapy live almost one year longer than patients with drug therapy. The cost-effectiveness ratio of ICD therapy in the study was $12,500. For modern devices that can be implanted in a pectoral, transvenous fashion and with device longevities exceeding four years, the cost effectiveness ratio is lowered to $7,500 per life year saved. This compares quite favorably to many other commonly applied therapies as shown in the following table.

Another important result of the MADIT trial points to the use of ICD implants as a means of primary prevention: In patients with reduced function of the left ventricle who already experienced myocardial infarction but did not yet show symptoms of arrhythmia the mortality compared to drug therapy was reduced by 54 percent by implanting an ICD.

The costs of ICD therapy were compared with those of other therapies in several studies\(^70\). In Germany in 1997, for example, the expenses of the health insurance schemes for anti-arrhythmic drugs were four times higher than those for ICDs.

Another study examined the treatment costs of patients in the year before and after the implant of an ICD\(^71\). The results of this Swiss study show that the costs of ICD therapy „pay off“ in approx. 18 months. The most important reasons for this relatively short pay-off period is the shorter hospital stay of ICD patients and the reduction in the number of hospital admissions after an ICD has been implanted.

### 6.7.6 The reimbursement situation for implantable defibrillators

Implantable defibrillators are implanted in hospitals and therefore reimbursed in accordance with the Bundespflegesatzverordnung on the basis of procedural rates (Sonderentgelte) and hospital per diems.

Procedural rate 9.05 applies to the "supply of an implantable defibrillator, including replacement" and since 1 January 1999 is rated at 55,040 points (i.e. with regional variations at approx. DEM
58,000). The amount for the reimbursement for the implant of a defibrillator was about 10% higher until late 1998 at 62,090 points.

The problem with the reimbursement for implantable defibrillators in Germany is currently not so much the amount of reimbursement. The problem is that hospital budgets limits the number of ICD implants that are paid for by the health insurance schemes. Budget limits do not allow centers to implant selected patients at risk who are threatened by sudden cardiac death.

The clinical evidence shows in an impressive way that the use of ICD therapy in certain groups of patients for primary as well as secondary prevention of sudden cardiac death is much more effective cost than drug therapy. From the point of view of cost-effectiveness it is in everyone’s interest that suitable patients benefit from the advantages of ICD therapy since the use of ICDs seems to be the more cost-effective treatment alternative in the medium and long term.
6.8 Case study 7: The treatment of intracerebral aneurysms with Guglielmi Detachable Coils (GDC)

Intracerebral aneurysms are thin-walled outpouching or dilatation of one of the large blood vessels that supplies blood to the brain. Interventional neuroradiology is becoming an increasingly important alternative to open neurosurgery in the treatment of intracerebral aneurysms. Minimally invasive GDC treatment ("coiling") is now considered an established procedure with costs considerably lower than those of surgical interventions.

The reimbursement situation in the treatment of intracerebral aneurysms provides a typical example for the ways in which the present reimbursement system in Germany hinders innovation. The payment of neurosurgical procedures usually occurs on the basis of per diem, so there is no financial incentive to reduce the length of stay. This hinders and sometimes even prevents the introduction of new minimally invasive procedures such as the GDC coil.

Present hospital regulations provide for so-called "trial projects" as a means for establishing adequate hospital rates on the basis of negotiations between hospitals and SHI funds. However, for a number of reasons, it has become increasingly difficult to negotiate and implement such trial projects. Without the appropriate financial incentives for hospitals, however, it will become even more difficult to introduce innovative and cost-effective procedures in the hospital sector.

6.8.1 Intracerebral aneurysms: definition and epidemiological data

An intracerebral aneurysm is a small, thin-walled dilatation of one of the large blood vessels that supply the brain. These so-called saccular or berry aneurysms can vary in size from 1 mm to 10 mm.

Intracerebral aneurysms can result from:

a) A developmental abnormality of the inside lining or intima of an artery with thinning of the blood vessel (which can become dilated under high blood pressure).

b) Infections of the blood vessels.

c) Traumatic injury of the blood vessel.

Intracerebral aneurysms are estimated to be present in 2 per cent of the population, and are often asymptomatic and thus not noticed by those affected. Approximately 15 out of 100,000 people suffer from a rupture of the cerebral artery.\(^{72}\) This so-called subarachnoid hemorrhage (SAH) is the leading symptom of an intracerebral aneurysm.

Approximately 15,000 patients suffer from an SAH each year in Germany. In more than 80 percent of the cases, a rupture of an intracerebral aneurysms is the cause of SAH. About 30 percent of the patients die before they reach a hospital. Of the survivors, 30 percent die while in the hospital and one third of the victims suffer long-term disability.\(^{73}\)
6.8.2 Treatment options for intracerebral aneurysms

6.8.2.1 Surgical treatment

The standard therapy for intracerebral aneurysms is the surgical clipping of the ruptured aneurysm. The introduction of a surgical clip stops the flow of blood into the aneurysm and thus the loss of blood through the rupture.

There is sufficient evidence that early intervention – two to three days after subarachnoid hemorrhage – can effectively stop the hemorrhage. However, the surgical procedure is technically difficult due to the inflammation of the brain and the ongoing hemorrhage. These and other problems led to the development of alternative endovascular techniques in the 1970s.

6.8.2.2 Endovascular treatment using the GDC

Catheter-based procedures are often used in interventional neuroradiology to treat abnormalities of the blood vessels in the brain without having to resort to surgical measures. The development of pliant platinum coils by Guglielmi (GDC) at the beginning of the 1990s represented a breakthrough in the treatment of intracerebral aneurysms.

With this so-called coiling technique, a specially marked microcatheter can be maneuvered into almost any intracerebral aneurysm directly after diagnostic angiography. A platinum coil is chosen that corresponds to the size and form of the intracerebral aneurysm and entered into the blood vessel using the microcatheter. The rupture or aneurysm can be treated using one coil or a combination of coils. The total time needed for the procedure, including diagnostic angiogram, is from one to two hours.74

The precise indications for endovascular therapy are still subject to debate. It appears as if patients with aneurysms in the anterior portion of the brain have the most benefit from the procedure. Patients with pronounced cerebral swelling and in poor clinical condition following an SAH (Hunt & Hess grades IV and V) are also potential candidates for endovascular treatment. An additional indication could be the management of incidentally discovered asymptomatic aneurysms.
6.8.3 Endovascular therapy with GDC: Data on efficacy, quality of life and efficiency

6.8.3.1 Efficacy

A multicenter study was conducted under the auspices of the FDA to analyze the safety and efficacy of this technique in the treatment of high risk aneurysm patients. Results are available for 150 patients with basilar aneurysms that were considered inoperable. In 107 of the 150 patients, the intracerebral aneurysm was completely closed in one sitting. Multiple interventions were necessary in 43 patients. The procedure led to at least a 90 percent closure of aneurysms in 75 percent of the patients. Cerebral embolies arose during the procedure in 34 (23%) patients and 12 patients (8%) suffered vasospasms. Four mortalities were recorded (2.7%), all in patients with ruptured aneurysms. The total mortality of this group was estimated to lie between 17 and 23 percent.

Other published studies also indicate the promise of this technology. A French group reported on the endovascular treatment of 256 aneurysms: 81 percent were closed completely and an additional 17 percent were closed by 95-99 percent. The results were unsatisfactory in only two cases. These results are particularly surprising since the first patients to undergo this treatment are usually those that are considered inoperable. With growing experience, however, an increasing number of patients with operable aneurysms are being treated by endovascular means.

Endovascular treatment is minimally invasive but not risk-free. The most common complications include thromboembolism. The published results indicate that the technically related mortality rates are between four and nine percent, and the procedural mortality rate approximately two percent.

6.8.3.2 Cost-effectiveness of endovascular therapy

American and British studies indicate that the costs for the surgical treatment of intracerebral aneurysms lie between $13,000 and $38,000. The main costs factor is the length of hospital stay.

The material costs for minimally invasive treatment with a GDC coil are approximately DM 8,000. In addition to this are the costs for one to four days of care in an intensive care unit and 1 week of care in the neurosurgery department. Assuming average per diems of DM 1,512 for an intensive care unit and DM 639 for a neurosurgery department, additional costs of DM 6,000-11,000 arise.

Total costs for a GCD treatment would thus range between DM 14,000 – 19,000 and are thus much lower than the costs of conventional surgical treatment. If ongoing studies reveal that the
length of stay in intensive care units and neurosurgery departments is lower than assumed here, GCD would clearly be a cost-effective alternative to conventional surgery.

6.8.4 The reimbursement situation for endovascular treatment with GDC

The treatment of intracerebral aneurysms is traditionally performed in hospital neurosurgery departments. The payment of the neurosurgical treatment is usually based on per diems, so there are no incentives to reduce the length of stay.

The diffusion of a minimally invasive procedure such as the GDC is hampered by this reimbursement situation as well as by the fact that the procedure is not performed by neurosurgeons but by interventional radiologists, who usually aren't associated with a specific hospital department that has beds.

As is the case for most innovative procedures, there are no case-related payments or procedural rates for GDC in the national catalogue of hospital rates. The procedure is therefore funded on the basis of hospitals' per diem rates, which due to the high material costs and short length of stay, are insufficient to cover the costs of the procedure.

A procedural rate has been introduced in Bavaria for the treatment of "aneurysms using a coil". Unfortunately, it is growing increasingly difficult to negotiate such trial projects. However, such trial projects are often the only means for introducing new and innovative procedures into the hospital sector at sufficient funding levels. Such reimbursement is becoming an increasingly important condition for the introduction of new procedures under the restrictions of limited budgets.

If measures such as trial projects are no longer possible, there is the danger that German hospitals will no longer be able to afford the introduction of many new technologies that shorten the length of stay, since the existing mode of hospital finance for these procedures, which is based on per diems, do not in general generate enough revenue per case to cover the costs of treatment.
6.9 Case study 8: Modern **in vitro** diagnostics for safe, rapid and economical diagnosis

In vitro diagnostics (IVD) are reagents for the analysis of bodily fluids and tissue. They are an important decision making aid in all sectors of the German health care system and make up only a minor portion of the expenditures of the Social Health Insurance (SHI) system (0.7 % of SHI expenditures on medical care). IVDs help in the early diagnosis and prevention of diseases. They allow for more precise diagnosis of diseases and thus contribute to an optimal therapy based on each patient's condition. In the treatment and management of diseases, they provide an easy and precise means for monitoring patients' progress.

The reform of laboratory reimbursement introduced on July 1, 1999 resulted in a dramatic decline in the utilization of special laboratory services, which include many modern tests and procedures such as the gene amplification process.

Furthermore, important screening tests such as the measurement of PSA and free PSA are not covered by the SHI funds, but are classified as "individual healthcare services" and must be paid for by patients.

Such regulations threaten the appropriate utilization of important laboratory tests. The sudden and massive changes in the laboratory sector indicate the need for guidelines on the use of modern laboratory services as a means for keeping modern laboratory diagnostics available to all who need them. Precise and early diagnosis with non-invasive IVDs not only benefits patients, it can also lead to considerable savings in other sectors of the health care system.

6.9.1 **In vitro** diagnostics and screening

Screening is the serial examination of a whole population, specific population group or group of patients. Its purpose is to detect disease at an early stage and, if possible, to prevent its occurrence.

One measure of the quality of a screening method is the power of its results, which is expressed in quantitative terms as its so-called diagnostic sensitivity and specificity. The sensitivity measures how many sick persons are also detected. Basically, the higher the sensitivity of a disease, the higher the probability that a disease will be detected by a test. The specificity measures the share of false positive results. The greater the specificity, the lower the probability that a test or other diagnostic procedure will detect diseases that aren't actually present.

On the basis of innovation and refinements in the area of laboratory diagnostics, new tests have been developed with higher specificity and sensitivity than existing diagnostic procedures. In many cases, modern in vitro diagnostics not only produce better results, they do so more rapidly and at lower long-term costs to the health care system.
6.9.2 Screening for chlamydia trachomatis

6.9.2.1 Chlamydia trachomatis infection

Infection with the bacteria chlamydia trachomatis (Ct) is the most common sexually communicated disease worldwide. The World Health Organization estimates that there are 90 million Ct infections worldwide. In Germany, the number of florid Ct infections is estimated at 1.1 million. The greatest prevalence is found among persons ages 20 to 24 (females: 5.9 %, males: 7.7 %), followed by the 15 to 19 years age group (females: 7.3 %, males: 2.2 %). The prevalence among pregnant women is estimated to be 2.1 per cent.

One characteristic of a Ct infection is that it often has few, if any, symptoms. Roughly 90 per cent of all CT infections are asymptomatic, and many of those affected aren't even aware that they are infected. The bacteria can remain in the body for years before any symptoms develop. If the infection is not treated, however it can cause other diseases and be transmitted to other people.

Risk factors for a Ct infection are: between 16 and 14 years of age, changing partners and unprotected sexual intercourse.

Some of the diseases that are caused by Ct infections in females are:

- urethritis,
- cervicitis,
- pelvic inflammatory disease (PID),
- proctitis,
- arthritis.

As the most common cause of PID, which often impairs tubal function and thus conception, Ct infections can also affect female fertility.

In males, the most common diseases that can result from Ct infections are:

- urethritis,
- epididymitis,
- prostatitis,
- conjunctivitis,
• arthritis.

Ct infections are not only transmitted through sexual contact. They can also be transmitted from mother to child during birth. It is estimated that CT infections are transmitted at birth in 60 to 70 per cent of the females who have the infection.

The results of this type of transmission of Ct infection are:

• conjunctivitis,
• respiratory disease,
• pneumonia.

The treatment of the Ct infection in both males and females is based on antibiotic therapy. If a Ct infection is detected early enough, the costs of treatment are therefore very low. Hospital treatment is only necessary for the treatment of chronic infections such as pelvic inflammatory disease.

No satisfactory treatments are available for the diseases affecting the newborn. Prevention is the best means for dealing with these cases.

6.9.2.2 The economic characteristics of different tests for the diagnosis of CT infection: conventional test versus gene amplification

Ct infections can be detected with different types of tests. The conventional diagnosis is based on a rapid test. These tests are inexpensive, but the results are relatively imprecise with a sensitivity of 64 per cent and specificity between 86 and 98 per cent. New test methods based on the so-called gene amplification method, provide results that are much more precise. Their sensitivity is approximately 95 per cent and their specificity lies between 97 and 99.7 per cent.

Since 1994, screening for CT infection has been included in the tests to be performed during pregnancy. A study conducted in 1998 analyzed whether the serial testing for CT infection makes economic sense. The analysis was based on a model developed in the USA that was modified to reflect German conditions and used to compare the conventional rapid tests with tests based on the gene amplification method.

The results indicate that the relatively high costs of the gene amplification method are more than offset by savings in other areas. Under the model assumptions, utilization of the gene amplification method could prevent the occurrence of disease in 700,000 persons and lead to total savings of roughly DM 380 million over a period of five years.
Furthermore, the model indicated that if females between 16 and 30 years and their partners were also screened for Ct infections, the prevalence of Ct infections could be reduced by 66 to 73 per cent within five years. The estimated savings would amount to DM 537 million.

6.9.3 The diagnosis of prostate cancer

6.9.3.1 Epidemiology and therapy of prostate cancer

Among German males, the incidence of prostate cancer is surpassed only by bronchial cancer. Each year some 22,000 new cases are diagnosed. The incidence and prevalence of this disease are strongly related to age. Less than one percent of the cases are found in males under 40. The incidence increase gradually up to age 60 and then rises sharply. Autopsies have revealed that almost all males over 80 have prostate cancer, even if this is not the cause of death.

Prostate cancer can usually be treated successfully when it is diagnosed at an early stage. Since the disease often has no symptoms in early stages, it may develop for years before it is detected. In Germany, 12,000 men die each year from this disease.

The standard treatment of prostate cancer is the surgical removal of the prostate (prostatectomy). The prognosis is usually favorable if the cancerous cells were contained in one half of the prostate and had not metastasized. However, prostatectomy can often cause incontinence and erectile dysfunction. If treated in later stages, the 10-year survival rates decrease to 20-30 percent. A metastasized prostate cancer cannot be cured. Early diagnosis is therefore crucial.

6.9.3.2 The diagnosis of prostate cancer

At present, the three most common methods for diagnosing prostate cancer are:

1. the digital rectal examination,
2. transrectal ultrasound exam (TRUS),
3. the measurement of prostate specific antigen (PSA) in a blood sample.

If the results of these tests indicate the presence of prostate cancer, a biopsy and histology are conducted to validate the results. 90 to 95 per cent of all prostate cancers can be detected on the basis of one or two biopsies.

The above-mentioned methods have various drawbacks. The sensitivity and specificity of the digital rectal examination depend to a great extent on the experience of the doctor who conducts the exam. Transrectal ultrasound and biopsy are difficult, expensive and uncomfortable for the
patient. Complications result in up to 16 percent of biopsies, the most serious of which are systemic infections and bleeding. PSA measurement using a blood test is therefore the most logical choice for screening purposes, since the method is fully automated and inexpensive and leads to good results in combination with a digital rectal exam.

Prostate specific antigen is a protein that is produced almost exclusively in the prostate gland. High PSA concentrations in blood can be caused by prostate cancer, prostatitis and by benign prostate hyperplasia. The latter condition is found among many elderly males. The threshold value used in tests is 4 µg/l. PSA is present as free PSA as well as PSA that is bound to the protein alpha1-antichymotrypsin. The sum of both fractions is called total PSA. Both total PSA and free PSA can be measured by modern laboratory tests. In the case of prostate cancer, the share of free PSA in total PSA is usually under 25 per cent.

Based on retrospective studies of archived blood samples it was demonstrated that in cases of prostate cancer elevated concentrations of total PSA can be found 6 to 10 years before the appearance of clinical symptoms. Thus, total PSA can be used in the screening of males (over 40). In a large multicenter study in Germany, 12,542 males underwent a digital rectal exam and total PSA measurement. A biopsy was conducted for suspicious findings of the digital rectal exam or a total PSA concentration greater than 4 µg/l. The interim results of the study reveal that in more than 50 per cent of the cases with prostate cancer, the PSA test alone led to a biopsy. The use of total PSA tests and digital rectal exams detects 2.5 times more cancers than the use of digital rectal exams alone. A US study of 6,630 patients in 1994 came to similar results. However, PSA tests are not covered as part of cancer screening among males over 40 years of age by the SHI funds. The fact that PSA tests are not conducted means that many cases of prostate cancer go undetected.

For total PSA concentration between four and 10 µg/l, the so-called "diagnostic gray zone", the diagnostic specificity of tests for the presence of prostate cancer is only 25 per cent. I.e., 75 per cent of all biopsies performed on these patients are negative. Since one third of all prostate biopsies are performed on this subgroup, there is an obvious need for tests that can avoid the necessity of biopsies and thus save costs as well as benefit patients. This is where the determination of free PSA can play an important role. If only those patients in this group with a free PSA ratio of less than 25 per cent undergo a biopsy, up to 20 per cent of the biopsies can be avoided. These results have been confirmed in different studies.

Recent studies also provide evidence that the measurement of free PSA allows a more sensitive detection of prostate cancer. If all patients with total PSA concentrations between 2.5 and 4
µg/l are also tested for free PSA, and a biopsy performed on all patients with a free PSA ratio of less than 10 per cent, it is possible to detect 30 per cent of the early stage cancers for which the total PSA concentration is less than the threshold value of 4 µg/l.

6.9.4 The reimbursement of laboratory diagnostics

In the ambulatory sector, laboratory services are reimbursed according to the doctors' fee schedule (EBM for SHI patients and GOÄ for privately insured patients). As discussed in Chapter 2, the EBM defines point values for doctor's services. The GOÄ specifies the doctor's fee in monetary terms.

Laboratory services are a special case in the EBM in so far as fixed monetary amounts are specified for each laboratory service. However, the reimbursement of doctors' services and laboratory services are subject to budget regulations. The services of laboratory doctors and of the laboratory services themselves are reduced in full up to a certain limit. Beyond this limit, the SHI funds pay reduced rates.

Furthermore, the utilization or performance of laboratory services by general practitioners and medical specialists have been subject to budget restrictions since July 1, 1999. If a doctor exceeds the individual budget limit, the costs of the services in excess of the budget limit are subtracted from the doctor's so-called "efficiency bonus". Each doctor therefore has an incentive to limit the number of laboratory services he/she utilizes or performs.

Once these laboratory budgets are exhausted, the doctor must make a decision: either decrease earnings by continuing to utilize laboratory services or limit the use of laboratory services and diagnostic methods that are very important for patients. If the doctor chooses the latter option, this can conflict with the patient's entitlement to medically necessary care and could even lead to liability problems.

The laboratory reform has been rightly criticized as being solely designed to bring about a drastic reduction in the amount of laboratory services. From the patient's perspective as well as the societal perspective is even more important that these measures, which lack quality assurance provisions, will result in a situation in which necessary diagnostic procedures are no longer utilized.

These considerations were confirmed by developments in the months following introduction of the laboratory reform: the number of so-called special laboratory tests, which include many of the new test methods, dropped sharply. In vitro diagnostic procedures such as the gene amplification method were particularly hard hit. In addition, medically necessary tests such as the measurement
of total PSA and, when necessary, free PSA are not reimbursed as preventive measures by SHI funds. The costs of these tests must be borne by patients.

Although it is too early to gauge the full effects on patients of the laboratory reform, it is likely that the medical objectives of rational diagnosis, prevention and treatment of diseases is not adequately reflected in the changes. As a result, diseases are likely to be detected too late or not at all, and treatment will focus on the symptoms instead of fighting the causes. It is also likely that laboratory test will be shifted into the hospital sector.

The sudden and dramatic changes in the laboratory sector point to the need for guideline-based laboratory diagnostics as a basis for improved quality assurance in the provision of laboratory services. Modern laboratory diagnostics must remain accessible to all patients as a basis for rational therapy. Early, safe and non-invasive diagnosis not only benefits patients but can also result in considerable savings in other sectors of the health care system.

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7 Reform proposals

7.1 Recommendations for the office-based sector

As described in Section 5.3.1, the admission of medical procedures and devices to the doctors' fee schedule (EBM) is a long and nontransparent process. At present, not all groups with a legitimate interest in the introduction of new procedures are involved in this decision-making process. Furthermore, there is no clear distinction between the tasks and responsibilities of the various committees and working groups that are engaged in the decision-making process. Given these conditions, there are four general measures that could be taken to expedite the introduction of new medical procedures and the associated devices and to ensure that patients have quick access to innovative medical technologies. The proposals focus on:

1. The application procedure
2. The composition of the committee(s)
3. The introduction of deadlines
4. The fusion of the responsible committees into a single decision-making body

The recommendations focus on increasing the transparency of the administrative procedure for determining the value of medical procedures and the transparency of the decision-making process for the review of new and existing procedures and technologies.

The proposals are intended to introduce mechanisms to ensure the equal administrative treatment of pharmaceuticals and new medical devices.

Under the provisions of the Health Care Reform 2000 (§33a par. 10 SGB V), pharmaceutical manufacturers may apply for admission of their products to the so-called "positive list":

"The commission shall update the list continuously to reflect the state of medical knowledge and new pharmaceuticals. After a marketing authorization has been granted for a product, the manufacturer can apply for inclusion of the product in the list..."

Thus, the legislation for the Healthcare Reform 2000 provides pharmaceutical manufacturers with the right to apply for the reimbursement of their products (Recommendation 1). Additional provisions in the original draft of the law also placed a limit of three months on the decision-making process of the responsible authority. If a decision were not reached within this time period, the pharmaceutical in question would be covered by the SHI funds until a decision to the contrary was made. Such provisions were included to ensure that the manufacturers would have a calculable basis for their investment decisions. The final provisions of the Health (§33a Abs.10
SGB V), which went into effect on January 1, 2000, are even more advantageous to pharmaceutical manufacturers: Following marketing authorization, pharmaceuticals can be covered by SHI funds until a decision has been made by the responsible authority (Recommendation 3).

7.1.1 The application procedure

The current administrative process for reviewing new diagnostic and therapeutic procedures with regard to their inclusion in the doctors' fee schedule (EBM) fully disregards manufacturers' efforts in the research and development of products. Although the marketing of a medical device requires the CE mark as proof of its quality, safety and performance, manufacturers must rely on the "good will" of the doctors' or dentists' associations or on that of a national association of SHI funds, who are the only parties that may apply for inclusion of a procedure in the doctors' fee schedule. In contrast to competitive market processes, the review process is a "second hurdle" to the marketing of a medical device. From the manufacturer's perspective, this shortens the already brief life cycle of a medical device and places additional financial risks on manufacturers, who must sometimes wait for extended periods before knowing whether a new product will be covered by the SHI system.

Allowing manufacturers or their representative associations to submit products for review would improve the quality of the decision-making process, for they are in the best position to provide information on the products and procedures in question. Expanding the number of potential applicants would not initially create any additional costs but serve to expedite the review of new diagnostic and therapeutic procedures. The need to include other interested parties in the decision-making process – such as patient groups – is less acute, since manufacturers themselves have a strong interest in the fastest possible review of their products.

7.1.2 The decision-making process of the committee

The decision-making process of the National Committee of Doctors and SHI Funds tends to neglect the legitimate interests of concerned parties such as manufacturers, their associations and patients. There is a real threat that short-term cost-containment objectives lead the committee to overrate cost aspects and undervalue the medical benefits for patients that are associated with new technologies and procedures.

Manufacturers should therefore be allowed to be present at committee meetings concerning the review of their technologies. This would make the decision-making process more transparent for manufacturers. Furthermore, in contrast to the present situation in which a formal written
decision is considered "final", manufacturers could make adjustments to their products or produce further documentation needed for the review process. Manufacturers' participation could be based on the principle of the "deliberative vote" (i.e. the manufacturer participates in the meetings of the committee, but has no voting right). This would offer advantages to the manufacturer while creating no disadvantages for the committee's action. In fact, the presence of the manufacturer at meetings could provide informational advantages.

Furthermore, it would be useful to assess the possibility of granting manufacturers a voting right in the committee decision-making process. While manufacturers could be granted a voting right with regard to the inclusion of a technology-based procedure, it is unlikely that this voting right could be extended to include the decisions on the level of reimbursement of a new procedure in the fee schedule.

### 7.1.3 Introduction of deadlines

Although measures based on the first two recommendations are likely to expedite the decision-making process, delays could still occur due to the lack of a consensus in the committee or other problems that arise during the decision-making process. Such delays are neither in the interests of manufacturers nor in the interest of patients, doctors and, ultimately, SHI funds. This applies especially to product innovations with positive benefit-cost ratios that provide patients with fully new diagnostic or therapeutic procedures.

Such delays may be prevented with the help of two different procedures for the introduction of new products:

One option is to allow coverage of a new medical device that fulfils the criteria of the Medical Device Act until a decision to the contrary has been made by the National Committee of Doctors and SHI Funds. If the committee makes a negative decision on a product and thereby prohibits coverage of a new diagnostic or therapeutic procedure in the office-based sector, then the procedure may be used only if a patient is willing to pay for it (such as the procedures in the IGEL List) or if it is covered by private health insurers. Such a practice would ensure that the introduction of medical devices in the SHI benefits catalogue would be equivalent to the introduction of new pharmaceuticals, and thus guarantee equal treatment of both. After all, medical devices and pharmaceuticals must undergo analogous procedures in order to enter European markets.

Another option consists in the introduction of deadlines to dampen the effects of extended delays in the decision-making process. If the committee does not make a final decision within a
legally defined period, a new diagnostic or therapeutic procedure would be included in the
doctors’ fee schedule automatically for an extended period of time.

The maximum amount of time for reaching a decision should be set at six months following
submission of an application. This should provide the committee enough time for the careful
review of a procedure and for a decision on its acceptance. Furthermore, changes in the structure
of the fee schedule that are related to the introduction of a new procedure could be analyzed
during this review period. The integration with the existing fee schedule should not be too
difficult and could be based on the currently used method of "analogous valuation".

Both options ensure that the often-dire need for innovative diagnostic and therapeutic
procedures is not met due to purely administrative delays. However, the equal treatment of
pharmaceuticals and medical devices is only given when medical devices are covered by the SHI
funds until the committee has made a negative decision. For this reason, coverage "until further
notice" is preferable to placing deadlines on the committee's decision-making processes.

7.1.4 Fusion of the existing committees

The current distribution of tasks in the committee for "medical treatment" (former NUB
committee) and the EBM committee results in a high degree of nontransparency for all interested
parties who are not allowed to participate in the meetings of these committees

Although the decisions of the committee for medical treatment generally have priority over those
of the EBM committee, the responsibilities of the two committees are not clearly defined.
Furthermore, it is highly inefficient that the first committee concerns itself with a procedure
while another committee concerns itself with the cost-benefit characteristics of technologies and
then determines how a procedure is to be introduced into the doctors' fee schedule. This
duplication of efforts on the same issue represents not only a waste of human resources, it is also
superfluous due to the fact that the decisions of the committee for "medical treatment" take
precedence over those of the "EBM committee". In the case that the decision of the first
committee is positive, the second committee "merely" has to make a decision on the
implementation of a new procedure.

These problems could be avoided by unifying all of the decision-making responsibility in a
single committee. This would not only tend to decrease the duration of the decision-making
process, it would also solve questions of legal responsibility.
7.2 Recommendations for the hospital sector

The following 12 recommendations reflect different issues that were discussed in the analysis of Germany's hospital sector. They deal with the recent modifications of the legal and economic basic conditions as well as general development trends in the hospital supply in Germany.

The recommendations are based on the following three questions:

- How can the hospital supply meet the special requests in Germany by the application of modern medical devices?
- How can medical devices provide maximum benefit in a hospital reimbursement system that is based on prospective per-case payment?
- How should a per-case-based reimbursement system be designed and how can it be adjusted over time to reflect medical developments and cost trends in order to gain as much benefit as possible from innovative and cost-effective medical technologies?

1. Budgeting in the hospital sector must be relaxed in order to ensure medical progress in the provision of hospital care.

The budget regulations for the hospital sector over the period of 2000-20003 limit hospital expenditures to the revenues of the SHI system. This will intensify the divergence between funding and the medical needs of patients.

Emphasis of the following points in public debate will increase the awareness for a policy environment that fosters innovation as the best means for fully utilizing the benefits of the increasing opportunities offered by progress in the medical sciences and medical technology.

- The appropriate use of innovative medical devices in the hospital sector is threatened by the strict budget limits in the hospital sector.
- This will have repercussions on the diffusion of new diagnostic and treatment procedures in the office-based sector.
- The spending restrictions in the hospital sector are likely to increase the discrimination of social health insurance patients compared to privately insured patients and self-payers ("two-tiered medicine ").
- Cost-utility considerations of the use of innovative and sometimes cost-intensive treatment methods in the hospital sector alone cannot analyze all relevant factors with
respect to benefits and costs. Rather, such analyses must include considerations the long-term effects on costs and benefits in the whole health care system.

- The strict budgeting and regulation of this important economic sector hinder the positive employment effects of the health care sector.

2. The decisions that must be made concerning the core elements of the new system of hospital reimbursement by 2003 should occur in the context of a constructive dialogue involving all concerned parties.

It is unlikely that there will be any substantial changes in Germany's system of hospital finance until introduction of the prospective payment system based on per-case fees for all hospital services in the year 2003.

The Health Care Reform 2000 contains little specification of the planned system for the remuneration of hospital services. Determination of detailed regulations is primarily the responsibility of self-management authorities. During the decision-making process, there must be active participation from all stakeholders. Important decisions must be made on the following issues:

- The definition of the patient classification system and the determination of the cost weights for the reimbursement system.
- The determination of "prices" for the lump-sum fees of hospital services.
- The continued development and adjustment of lump-sum fees over time to accommodate medical developments and cost trends.

A constructive dialogue involving all concerned parties, including the responsible self-management authorities and the German government, is called for. This would allow different perspectives and considerations to flow into the decision-making process and increase acceptance of the new regulations on hospital finance.

The results of the dialogue should also be reflected in the Hospital Fee Ordinance that is to be developed by the German Ministry for Health by the year 2003.

3. In order to ensure that the patient classification system is defined in enough detail, it is necessary to ensure that classification is based on therapeutic measures as well as patient categories.
The national patient classification-system will provide the foundation for the planned service-based lump-sum reimbursement of hospital services. The self-management authorities must decide on the basics of the system by June 30, 2000.

In order to keep the hospital sector open to the utilization of high-quality medical devices and to the introduction of innovative medical devices, five issues need to be addressed:

- The patient classification system must be characterized by an adequate amount of detail.
- It is particularly important that the factors of co-morbidity and complications given appropriate consideration.
- Therapeutic measures must be given enough weight in the construction of patient categories and the classification of patients.
- The DRG-patient system called for in the Health Care Reform 2000 must be adapted to fit the German hospital sector.
- Although the All Patient DRG system (AP-DRG) is an appropriate starting point, it is less detailed than the present Fallpauschalen and Sonderentgelte with respect to medical factors. Such deficiencies must be amended before a new system is used on a national scale.

4. In defining the relative cost weights for each patient category, it is necessary that the main medical specialties needed in the provision of hospital care for each category be considered explicitly.

Under a DRG-system, each patient is assigned to a patient category. The cost weights determine the relative level of reimbursement paid to a hospital for the provision of care to patients. Care provided to patients in a given category is reimbursed at a single level.

In order to ensure the provision of adequate care, the following factors should be observed in the definition of the cost weights for the each patient category:

- The direct transfer of cost weights from foreign systems is inappropriate.
- The cost weights should be calculated for each patient-category separately.
- A representative sample of German hospitals must be used as the basis for calculation.
- The use of particularly cost-intensive medical devices is to be considered explicitly in the calculation of each patient category.
• The plausibility of the calculation results has to be checked by comparing them with the cost weights that are already in use in other countries.

5. The planned DRG system must be adjusted regularly and promptly to reflect progress in medical technology and cost trends.

The self-management authorities must decide by 30.06.2000 on the basic procedures for developing and adjusting the lump-sum reimbursement system to reflect medical progress and cost trends.

To ensure that all hospital patients have immediate and direct access to innovative procedures in the future, the procedure for the adjustment of the planned reimbursement system should differentiate between three phases:

• Immediately after the certification of a medical device (CE mark), hospitals that use the device in the course of diagnosis or treatment should be able to request reimbursement of costs from the patient's SHI fund.

• When a new medical device is already used on a limited basis in clinical practice, there should be a procedure for determining provisional reimbursement that is valid for all SHI funds.

• The final definition of the reimbursement level for a procedure should take place in the context of a process for the annual update of the reimbursement system.

The overall objective must be to ensure the continuous and appropriate adjustment of the reimbursement system to reflect innovation. Depending on specific circumstances, phases 1 and/or 2 should also be allowed to be bypassed.

6. A DRG system should not be used only as a means for determining hospital budgets; it should also be used in the medium term to establish a flexible pricing system for hospital services.

If a DRG system for budget calculation is implemented beginning in the year 2003, it is likely that there will be considerable shifts in the allocation of total hospital expenditures within the hospital sector. In order to maintain a decentralized hospital system, some hospitals must receive compensation. This compensation should

• result from price negotiations with individual hospitals and

• apply for a limited period only.
Such a negotiation system would be a first step towards the use of a DRG system as a flexible pricing system. Negotiations between health insurers and each hospital would then be based on a uniform patient classification and focus on the price of hospital services. On the basis of such prices, the specific situation of each hospital would determine its range of services and specialities.

As a next step towards a flexible pricing system, individual health insurance funds should be granted the right to enter into selective contracts with providers. This would allow health insurers to negotiate separate contracts with hospitals for the use of modern medical technologies.

The allocation function of the planned patient classification-system can be best utilized if it is used in conjunction with such a flexible pricing system that directs resources to the most efficient applications.

7. **Co-operative approaches to the introduction of innovative medical technologies in the hospital sector should be granted a more prominent role as a means for maintaining the standard of medical care.**

The change to a DRG-based system for the remuneration of hospital services will promote reorganization in the hospital sector. Increasing concentration and specialization in the hospital sector will intensify the pressure on the players in this sector to act in co-operation.

Strategic alliances among equal partners for the introduction and application of medical innovations can make it easier to adjust to these changes. Such alliances are also an important way to ensure the immediate access of patients to the most modern treatment methods in the hospital sector. The benefits that result from such alliances are:

- Co-operation among hospitals (public and private), health insurers and industry is a prerequisite for the local testing of medical-technological innovations in the context of clinical and practical trials.

- The co-operative implementation of "risk sharing models" promotes the introduction of medical innovations.

- Co-operative approaches would allow individual hospitals to evolve into "centers of excellence" by gaining extensive experience in certain procedures or the treatment of certain diseases.

- Increased co-operation in the health care system benefits all parties and has positive effects on the quality and efficiency of health care.
8. The planned procedure for the review of medical innovations in the hospital sector on the basis of Health Technology Assessment must allow for the participation of affected parties in the context of an objective and transparent procedure.

The legal provisions for the "Hospital Committee" call for the self-management authorities to introduce flanking measures. The following principles should be observed in the establishment of the functions, organization, and mode of operation of the "Hospital Committee".

- The committee members should be independent and impartial experts. For special issues, external consultants should be consulted.
- It is recommended that the industry be granted the right to request the initialization of a review procedure. It is indispensable that industry has the right to be heard in the course of the review process.
- The committee should focus on the medical benefits and medical necessity alone.
- The evaluation procedure should not affect clinical and practical trials of innovative medical devices.
- The decision-making procedure should be transparent and manufacturers should have the right to appeal.
- There should be a strict timeline for decisions (6 months).
- The "Hospital Committee" should work closely with the "National Committee of Doctors and SHI Funds".
- The "Hospital Committee" should work closely with the committee that is responsible for the adjustment of the DRG system.

9. National and international experience should be integrated in the creation of binding clinical guidelines in order to avoid hindrances to the application of medical and technological innovations.

An important function of the "Co-ordinating Committee" is the creation of binding guidelines founded on evidence-based medicine. Clinical guidelines will play a growing role in the utilization of medical devices in the hospital sector. The following factors should be observed in the creation, introduction, and adjustment of clinical guidelines:

- The results of clinical studies performed in the research and development phase of medical-technological innovations should be used for the creation of guidelines.
• The results of local clinical trials of new medical devices should be reflected in the creation of guidelines.

• National and international data should be used.

• Clinical guidelines should define clear indications for the use of important medical devices.

• Guidelines should be adjusted promptly to reflect medical and technological innovations.

10. **The cost effectiveness of innovative medical devices should be tested in selected hospitals (centers of excellence) immediately after their certification.**

Experience in other economic sectors suggests that a meaningful evaluation of the efficiency of an innovative device or procedure is best performed in individual hospitals. This means that:

• Provisional reimbursement agreements should be made at the level of the individual hospital immediately after a device is granted a CE mark. Such agreements could be based on provisions like the current regulations on trial projects in the hospital sector, which allow for local reimbursement agreements between SHI funds and hospitals. International data could be used to determine the level of provisional reimbursement.

• Clinical trials and practical tests of new and innovative procedures in selected hospitals should also be used to evaluate the economic characteristics of these procedures.

• Individual hospitals can thus evolve into so-called "centers of excellence" for new treatment methods.

• The clinical results could be included in the decision-making process of the "Hospital Committee".

• The results of local clinical trials can be used for the general introduction of new products and procedures and for the definition of reimbursement levels.

11. **The "sovereignty" of patients and the insured in choosing therapy should be enhanced through the provision of targeted information.**

Patients' need and desire to have a stronger say in the choice of therapy is part of a general social trend. In particular, patients want more first-hand information on the benefits and risks of medical procedures. A good information basis will help promote the diffusion of medical and technological innovations.
The prerequisites for the increased participation of patients in the choice of medical procedures are:

- Knowledge of available treatment alternatives.
- Information on the characteristics of procedures that is of relevance to patients.
- Information on hospitals and healthcare facilities in which innovative procedures are used.

The prohibition of direct advertisement by hospitals ensures the objectivity of the information.

The role of self-payers and the privately insured with respect to medical and technological innovations in the hospital sector provides the basis for the general introduction of new procedures in the health care system. This plays an important role in the optimization of hospital care in respect to the medical needs of the patients.