Chapter 10
Reimbursement Systems for Healthcare: Considerations on "Pay for Performance"

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Abstract Demographic changes, limited healthcare budgets and performance-based attitudes for medical therapies have led to Pay-for-performance programs in healthcare. Here, consumer (patient), provider (physicians and nursing staff) and payer (patient and health insurance funds) are all involved. To reach targets based on measurable quality indicators, incentives are provided for the efficient use of medical resources and medical devices. The establishment of such key factors needs a consensus among the involved stakeholders to be successful. This consensus can only be reached if the interests of these groups are balanced, beard in mind and special attention is paid to such a complex process. Artificial intelligence-based analyses of large patient databases may be of help in improving this situation. Medical devices underwent a metamorphosis from a simple instrument to a complex tool allowing for sophisticated performances and the active, online interaction with treatment modalities. Innovative devices allow for covering preventively responsibilities in medical care and impact disease management. Vertically structured companies can serve as a model for successful corporates in medical device technology.

Introduction

Public expenditures for health care reach on average the total of 9% of GDP in most industrialized countries according to the Organization for Economic Cooperation and Development (OECD). There is a clear positive association between healthcare spending per capita and life expectancy. Depending on risk factors, countries with

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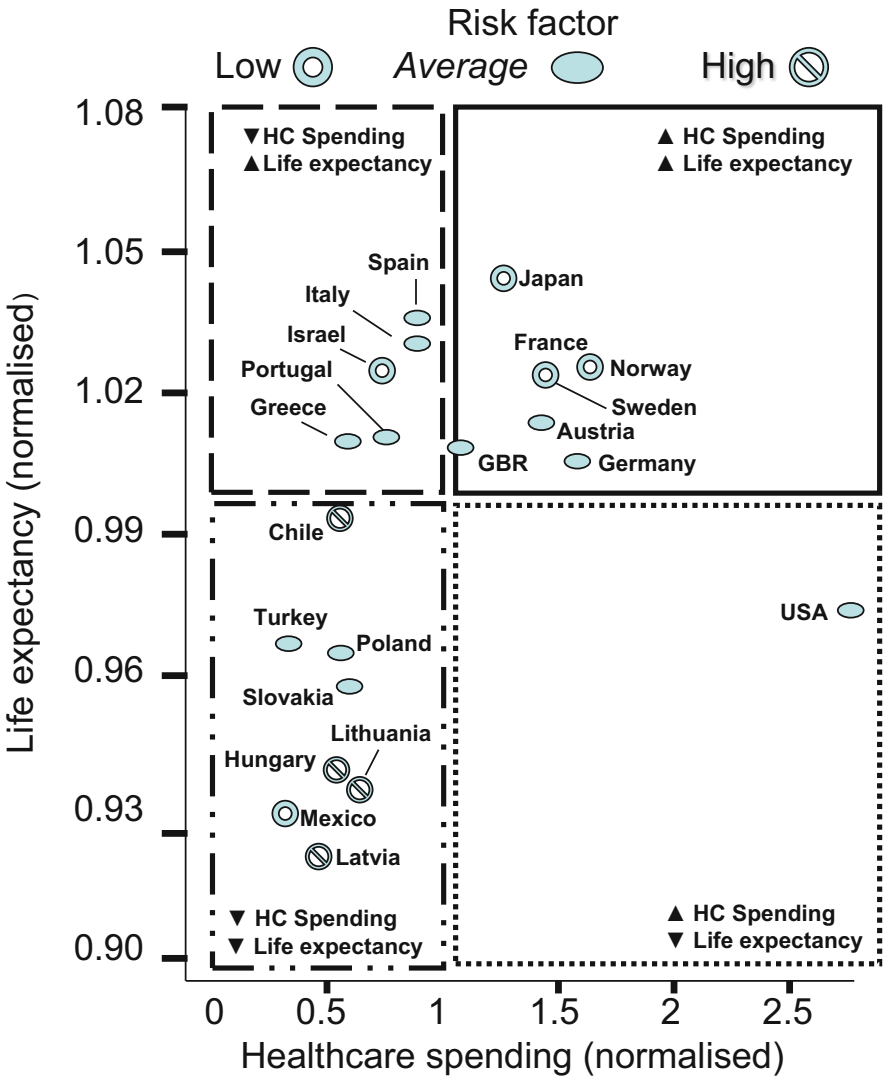

Fig. 10.1 Health care spending, life expectancy (arbitrary units) and risk factors in different countries. There are countries with low healthcare expenditure (upper left-hand panel) but with increased life expectancy. Compared to other countries, the USA (lower right-hand panel) exhibit a moderately reduced life expectancy despite high expenditures on healthcare. (Adapted from [1], *GBR* Great Britain)

the highest health care expenditures (HC spent) however, do not automatically show the best results in this realm (Fig. 10.1, [1]).

As shown in Fig. 10.1, there are still improvement opportunities in both healthcare efficiency and healthcare expenditure. Currently observed changes in

demography have a strong influence on both factors. An increased number of elderly people will depend on a more intensive care and thus create higher levels of related cost. Further, the development of both, high-cost medical devices, therapies and pharmaceutical agents for individualised therapies imposes already to date a high pressure on healthcare budgets. Consequently, the search for measures to increase both, efficiency and performance, as well as the identification of related guiding factors have become a matter of debate since many years [2–4].

In addition, recognising the growing prevalence of value-based care, medical device companies are increasingly incorporating risk-sharing programs into their customer agreements. Conceptually, these efforts are a step towards aligning medical device suppliers and hospitals to providing value-based care. In the context of shrinking margins and the striving for a concept towards value-based care, risk- and budget-sharing contracts with medical device manufacturers and other healthcare stakeholders hold significant promise for healthcare systems. This affects all stakeholders, if they are fully informed about related financial consequences before entering these arrangements. Mutually accepted quality indicators are a *sine-qua-non* condition when considering value and risk in healthcare.

10.1 Pay-for Performance and Clinical Therapies

Hospitals measure the patient's length-of-stay and many use this measure as a surrogate marker for quality and efficiency. Questions arise whether this first metric is also considered by patients when thinking about hospital quality. Even from an administrative point of view, the financial benefit of a patient's reduced length of stay cannot be realised, unless cost of labour is reduced at the same time.

At the onset of the 1960s, such debates have been advanced and investigations have been performed about "Pay-for-performance (P4P)" programs in the United Kingdom (UK) [5] followed by the USA in the later 1990s [6]. They circulated around efficient and high-quality healthcare systems, because published data have revealed inefficiencies in the British healthcare system [7]. Central questions arose already at that time on how to define key figures for assessing performance, quality and efficiency in order to find a measure for an adequate payment [4]. Given that such figures are identified, improvements in the status-quo of healthcare systems are possibly realized both in a timely and long-term manner [8]. A general approach to get an understanding of "performance" in this chapter and defining value in healthcare can be taken by:

$$\text{Value} = \frac{\text{Quality of Care} + \text{Services}}{\text{Cost}}$$

where "Cost" combines medical cost and nonmedical cost. Medical costs comprise both therapy and hospitalisation cost, medication, outpatient care and patient-

transportation, whereas nonmedical cost refer to productivity losses of patients and caregivers, as well as cost related to environmental burdens.

Improving Quality of Care, especially for patients with chronic diseases, is generally realized by financial and nonfinancial incentives for physicians and care givers. Today, healthcare providers and payers spend substantial resources collecting, analysing and reporting data on providers' performance. Associated negative aspects and undesirable consequences have to be minimized by optimising such incentives in the long run.

Based on experiences in the UK, many countries have recently started with "Pay-for-performance (P4P)" programs in healthcare, mostly for the management and therapies of chronic diseases, such as e.g. diabetes [9, 10]. They focus on both, quality of care and quality of life (QoL) in affected patients [8]. Still to date however, many of the P4P programs lack long-term experience and thus, contradictory and non-reproducible results are still common [11].

10.1.1 Pay-for-Performance (P4P) Programs

Pay-for-performance (P4P) programs in healthcare are based on control mechanisms which allow for the quality improvement of medical therapies whilst strictly coping with current limited healthcare budgets. Patients and healthcare providers further determine boundary conditions which are set by both, the general health situation of a defined population, and by a currently diminished availability of care givers. For instance, on the one hand, the patients' performance depends on their individual health behaviour including risks, such as a high body mass index, the deliberate exposure to infection or underlying noncommunicable diseases. On the other hand, healthcare providers face general healthcare problems, such as demographic changes or the impact of policy decisions. All stakeholders must cope with mutual benefits, claims and payments, whilst all parameters depend on healthcare resources, available expenditures and funding (Fig. 10.2).

In addition, adequate allowances for physicians and caring staff should positively contribute to quality of life (QoL) and a healthy and productive ageing of patients. A performance- and quality-based reimbursement system for ambulant- or hospital-based therapies, a so-called P4P program aims at providing solutions and a way-out from budget constraints in healthcare. P4P is currently advanced by two different models:

1. **Prospective model**:
   Bonus payment for achieved performances in advance.
2. **Retrospective model**:
   Reimbursement of performance depending on the assessment and analysis of preassigned key factors.

Both models depend on targets and key figures which may change according to actual boundary conditions. Consequently, "P4P is not a magic bullet" as it was

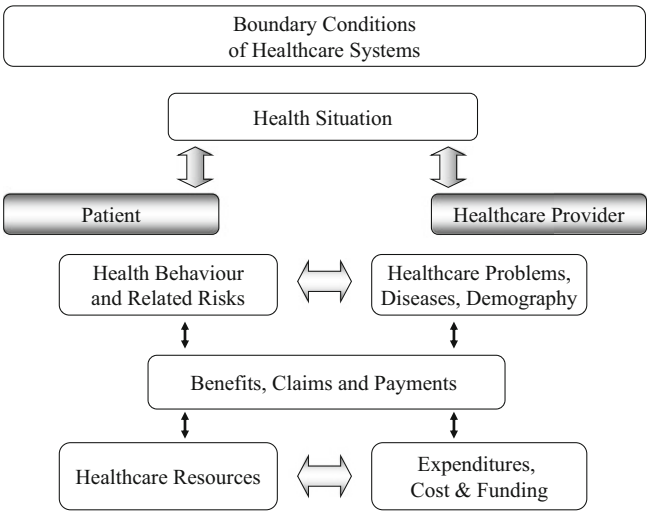

Fig. 10.2 Interdependencies of patients and healthcare providers in terms of mutual benefits, claims and payments (own representation).

explained by M. Roland [12]. P4P systems need to be strategically and continuously adapted to the stakeholders' actual needs to sustain improvements in the quality of care in the long run.

The general premise of P4P is based on the assumption that physicians in charge will react positively on financial and nonfinancial incentives and can thus be motivated to improve their performance and to successfully reach predetermined targets [13]. However, and unfortunately, a convincing general proof of efficiency shown by existing P4P models cannot yet be demonstrated [6, 11, 14]. Possible reasons are incentive systems which depend on location and type of hospital, limited healthcare budgets and increasing material and labor cost, as well as problems in defining and assessing therapy quality. Overall, it must be assumed that special local overall conditions exacerbate the identification of key indicators for clinical efficiency [6, 11].

10.1.2 Determining Factors for the Introduction of P4P Programs

Boundary conditions for P4P models are highly relevant for the development of P4P systems. Before introducing P4P programs, determining bystander conditions have to be identified, defined and modelled at an early stage. These factors include the type and organisation of national healthcare systems and the amount of available

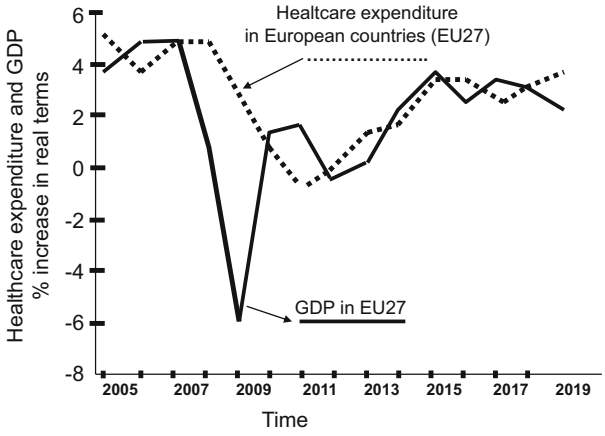

Fig. 10.3 Percent changes in annual healthcare expenditure and gross domestic product (GDP) in real terms. (Adapted from [15])

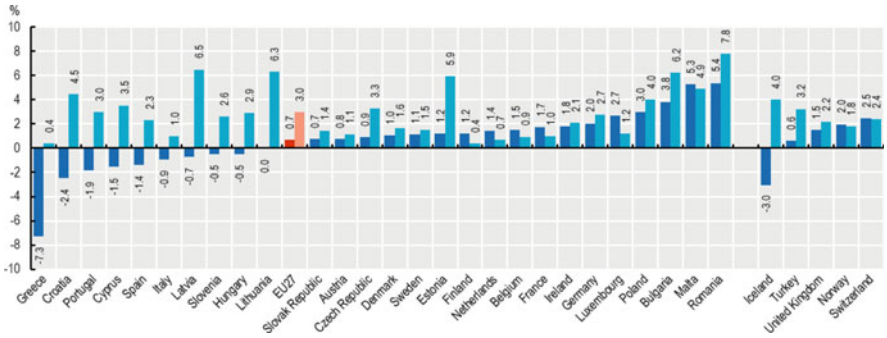

Fig. 10.4 Percent growth rates in expenditures for healthcare *per capita* in European countries (2008–2013 dark blue bars) and 2013–2019, bright blue bars). All European countries show an increase of health expenditure between 2013 and 2019. An average of 3% increase is found for the EU27 in this period. (Adapted from [15])

healthcare budgets, the number of affected patients and their age distribution in related areas.

In European countries (EU27), healthcare budgets in comparison to the GDP have reached a plateau in recent years (Fig. 10.3).

It is noteworthy that healthcare expenditures computed per capita have increased as well (Fig. 10.4, [15]). Reasons for this notion are changing demographic factors, i.e. an increasing number of elderly people, an improved healthcare availability and the use of perfected and possibly expensive medical devices. Data from Germany support the notion that the number of elderly people is currently rising [16]. The number of people with advanced age (80 years and more) increased by 4.5%

between 2011 and 2020 and reached 5.9 million (7.09% of the total population [17]). Actual forecasts guestimate an even higher figure in this cohort for the next decades. When the birthrate will reach a level below the so-called "compensatory level", problems in per capita healthcare budgets will become even more pronounced. The "compensatory level" refers to a birthrate which is necessary to maintain the actual population number. When birthrates drop and the number of elderly people increases, healthcare cost per capita cannot be covered by the younger generation in the future. It is, therefore, reasonable to ask whether P4P models as a preventive action can help to overcome these problems.

10.1.3 Motivation of Involved Stakeholders and Their Possible Conflict of Interest

It is generally assumed that performance-based allowances can contribute both to an improved healthcare quality whilst keeping cost under control. The success of P4P models however, depend on how early possible conflicts of interest between the involved stakeholders are identified and qualified. Unfortunately, a general consensus between the different stakeholders in healthcare provision does not exist yet. A common understanding is mandatory of why and how quality indicators of a therapy success are applied. Only hereunder acceptance of all stakeholders can be guaranteed despite certainly existing different conflicts of interest [17].

In the following, we provide an overview of those stakeholders who determine the success of a P4P program.

Patients as Stakeholders

Patients are to date better informed and seek validation and guidance during therapies. They demand the provision of adequate healthcare technology, have a close look on process quality during treatment and expect treatment experience and personal involvement by caregivers. Consequently, patients enjoy top priority in all P4P programs. These programs start from the premise that the patient's QoL will be improved if more efficient medical devices are used and therapies are provided more closely in time. However, the success of a therapy depends on both the subjective feeling of a patient in terms of e.g. perceived quality of treatment, her/his mental health and her/his initial clinical situation. In addition, patients link "quality" not only to an outstanding clinical treatment but also to both a sympathetic attention of nursing staff and explanatory communication skills of physicians in charge [17]. Such skills impact patient compliance and therefore determine the positive treatment outcome.

The mutual cooperation of patients with the respective doctor and thus their compliance depends on socioeconomic aspects, i.e. their individual medical records

combined with their private cost sharing. In healthcare systems without statutory health insurances, cost sharing is high and the impact of patient compliance is more pronounced. Further, patients have often only limited or asymmetric knowledge and information about necessary therapies, such that they are unable to judge the need of a medical therapy, the application of a costly medical device and its best achievable result. Consequently, an active cooperation and a transparent communication between physicians and patients are necessary conditions for metrics to improve clinical quality and performance.

Physicians as Stakeholders

Physicians represent the executive body in P4P programs. Defined medical outcomes are determined by the physicians' performance which is, therefore, addressed by P4P allowances. Typical P4P programs provide additional remunerations given that medical records improve in a defined period of time. Physicians, who participate in P4P programs, are prone to achieve good therapeutic results through efficient treatment modes and best-performing medical devices [17]. In this context, a conflict of interest between patients and physicians cannot be excluded. Patient welfare can turn out to be even subordinated, if high financial incentives are provided for applying specific treatment options. In contrast, the social and personal reputation of a physician is recognised by premium-quality of care and is last-but-not least determined by medical ethos. P4P programs, however, may also have a negative impact. For instance, British physicians were afraid to lose their autonomy and their professionality after the introduction of P4P programs. They argued that the nursing staff will be responsible for their medical activities due to cost and time constraints [5].

P4P programs are no stand-alone systems. They allow to compare the efficiency of physicians, outpatient centres and hospitals. When documented, patients might be willing to change the doctor in charge due to their respective delivered performance, which finally motivates the doctor to improve his personal performance.

Hospital Management as a Stakeholder

The hospital management is assigned to coordinate P4P programs and is in charge to identify organisational tools and modalities to reach predetermined P4P targets. The success of these activities depends on whether targets are mutually accepted by the clinical stakeholders, whether performance indicators are reasonable and how existing therapy standards can be modified [7].

The hospital management obviously has to focus first on patient satisfaction and both therapy performance and success, not neglecting the access to healthcare provision [7]. These aspects also determine the incentive commitment for physicians, which should motivate physicians to improve their performance.

The primary goal of the hospital management is focused on increasing cost-efficiency. By improving therapy quality and optimising medical device resources, medical malpractice should be minimised which finally should lead to a reduced hospitalisation.

Health Insurance Funds as Stakeholders

Health insurance funds top the hierarchy of P4P programs. They define the targets in healthcare to be reached by the stakeholders involved. In addition, they settle financial means necessary to reach the appropriate targets. Under the control of health insurance funds, treatment costs are determined by available healthcare budgets, which finally predefine quality and orientation and targets of health services. The basic interest of this stakeholder is to provide appropriate medical benefits with high efficiency at minor cost. When introducing P4P programs, health insurance funds further expect to reduce cost related to over- and under supply of prescribed medical devices, as well as to inappropriate healthcare. The establishment of healthcare standards could help in this regard.

It must be mentioned however, that health insurance funds—as a disadvantage—have to bear in mind and prioritise the interests of several principal actors.

10.1.4 Case Report: The P4P System in the United Kingdom

A few decades ago, there was little effort to assess the performance of healthcare systems due to a general agreement that healthcare quality and medical treatment was unmeasurable. Therefore, no agreement among the involved stakeholders could be simultaneously reached about the nature and dimension of "quality indicators". Today, healthcare providers spend substantial resources collecting, analysing and reporting data on providers' performance and link their efficiency to variable incentives [4]. In 2004, the United Kingdom introduced one of the World's largest Pay-for-performance programs, the "Quality and Outcomes Framework (QOF)". Within this framework, data on medical expenditures and medical personal were recorded in relation to the income of family doctors and special hospitals for patients with chronic diseases were established. The British Government provided additional funds of 1.8 billion £ over 3 years and by this means increased the income of family doctors by 25% as an incentive for a better therapy quality [18].

Already in the beginning of realising the P4P programs, it became clear that P4P models are highly suitable for the documentation of successful therapies in chronic diseases. For instance, pharma-, research- and medical opinion leaders agree upon saying that chronic kidney patients and the treatment of haemodialysis are keys to innovative concepts of care [19].

The following actions have been taken in the UK in 2004:

1. Establishment of a set of quality indicators consisting of 147 key figures from four different quality domains, such as clinical processes and structure, patient outcome and patient satisfaction.
2. Round-up of key figures to a maximum of 1000 points in order to determine a final score for the determination of payments.
3. Payment of 120 £ per achieved point.
4. Establishment of "exception-rules" as a risk adjustment. Due to administrative or specific medical reasons the therapy of patients, who deny a therapy or suffer from actually occurring additional diseases, can be excluded from the quality indicator benchmark.
5. Application of "Electronic medical record systems (EMR)" to document medical interventions and to identify medical therapy improvements.
6. Annual readjustment of QOF by the British Medical Association and the Department of Health.

10.1.5 Results: General Observations

The P4P program realised in the UK in the last decades concentrated on the prevention and treatment of chronic diseases due to a given simplified control of impacting parameters. Since the introduction of the QOF, verifiable improvements were seen in the British healthcare service. However, a precisely controlled definition of quality indicators and a closely controlled analysis of type and delivery of incentives render a clear-cut conclusion about advantages or even disadvantages difficult. As a program, which was endowed by the British Government, subsidiaries were limited in time and did not finally yield general structural changes. Despite additional bonus payments for physicians, hospital administrations had to make substantial investments into data recording systems in order to reach quality targets. This was a handicap especially for low-performers in the P4P program.

It can be assumed as an outlook, however, that the enormous actual increase in data storage capacity, combined with intelligent analytical tools, the evaluation of patient data will allow for a better targeting of aims and goals in future P4P programs. Indeed, a significant rise in patient data is also linked to newly available noninvasive sensors for physiological parameters. They will allow for a closely linked scalability of incentives for both hospital administrations, nursing staff and physicians. Future P4P programs also have to take data-protection and -anonymisation into account, which makes it difficult to obtain a reliable assignment of achievements to one or the other stakeholder.

10.1.6 Results: Improvements in Clinical Quality Indicators

The introduction of P4P programs in line with the Quality and Outcomes Framework (QOF) has led to substantial clinical benefits. When looking at specific diseases, such as diabetes, pneumonia, asthma and coronary heart disease, quality scores rose continuously [5, 14]. For the endpoint “mortality” however, no significant differences could be observed when comparing control regions with a verum group in North Western UK (Fig. 10.5, [14]).

10.1.7 Lessons Learned from QOF Daily Practice

Key elements for the improvement of medical treatment need to be those quality indicators which allow for an objective and reliable assessment. Those indicators are both, multifactorial and multidimensional and are characterised by the following criteria [17]:

1. **Validity** criteria have to be determined by a committee of experts.
2. **Sensibility** and reactivity for changes and modifications.
3. **Reproducibility** under multiple medical conditions.
4. **Acceptance** by all stakeholders.
5. **Measurability** even for different disease states.

Lessons learned during the introduction of QOF, show that management structures, workflow processes and patient outcomes impact key quality figures to a high degree [20]. **Structural parameters** take into account the value of staff qualification and material resources. They are directly linked to the availability and performance of medical devices. Strategies for the improvement of high-value care depend on how these resources are available and efficiently used. **Workflow indicators** allow for documenting patient data and related information as well as details on the

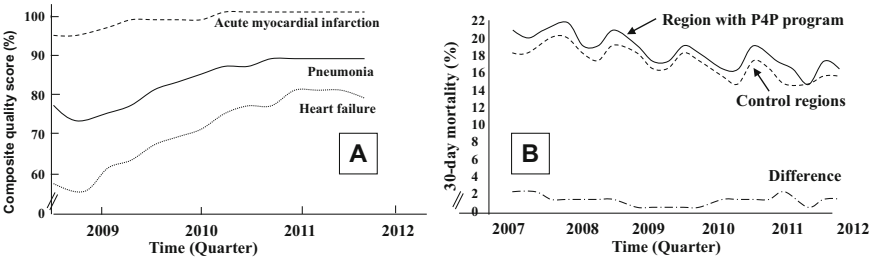

Fig. 10.5 Average hospital performance on quality scores for three clinical conditions linked to incentives in a P4P program in UK (**a**) and paralleled in hospital mortality at 30 days (**b**). Whilst hospital performance improves over 4 years, no difference can be found between regions exposed to a P4P program and control regions for %-mortality under the same conditions. (Adapted from [14])

performance of individual clinical treatments and prescriptions for medicinal drugs [17]. For instance, in QOF the number of patients is covered by workflow indicators, who have been treated by defined clinical guidelines. It is possible to easily and continuously measure workflow indicators. They are, therefore excellent P4P indicators, as they also allow for the precise information on the performance of physicians in charge. Finally, data on **patient outcome** determine to a high degree whether a treatment was successful. Data on patient outcome can be defined by the following 5 D's [21]:

- **D**eath. Despite a defined treatment, death cannot be avoided.
- **D**isease. Symptoms and clinical sequelae can still not be avoided.
- **D**iscomfort. There is still a number of adverse reactions, such as pain.
- **D**isability. The treatment leads to an impairment of body functions.
- **D**issatisfaction. Patients still suffer from a therapy and show personal discontent.

The success of a treatment needs to be qualified by both, the judgement of the doctor in charge and the subjective perception of the patient. This correlation has proven to be important. Perceptions on the patient's QoL strongly depend on her/his actual health condition and the capability to cope with her/his individual situation. For instance, two patients with the same degree of sickness can still show different sensations of their QoL [22].

As a conclusion, no supporting observations and evidence can be reported that hospitals, whilst having operated under P4P programs for a longer period of time, had a lower patient mortality than other hospitals. This suggests that even under an increased observation time, it is unlikely that under the current conditions P4P programs will turn out to be successful in the future [6].

Future schemes for improving healthcare need to focus especially on the elderly population with its deteriorating physiological conditions, because the subsequent risk to develop chronic diseases leads to an increased care dependency. Prevention measures should be included in scores to describe healthcare performance as additional quality markers [23].

Further, an iterative approach in terms of *design thinking* for the creation of value should be initiated and is recommended. With *design thinking* solutions can be obtained for a better understanding of the position and needs of users (physicians, caregivers, patients and other providers), and assumptions for a better performance and routes to redefine value in healthcare can be elicited. *Design thinking* approaches in healthcare are able to enhance innovation, efficiency, and effectiveness [24].

10.2 Performance and Compensations for Medical Devices

Pay-for-performance programs have neglected the role of medical devices and their specific contribution to treatment quality. The question arises, whether a special focus on device performance or on innovative device features may contribute to healthcare quality and thus to its value. In the following, we will discuss recent

trends and changes in the medical device market and identify the new role of medical device manufacturers.

10.2.1 Trends and Observations in the Global Medical Device Market

Health and healthcare are influenced by many key factors, such as *patient medication* and *nutrition, cosmetics* and *treatments with medical devices*. Further, medical devices are not exclusively applied in ambulant and clinical therapies. They also play a significant role in in vitro diagnostic analyses and are therefore addressed by a recently issued EU regulation the "IVDR in vitro diagnostic medical device regulation" [25]. The IVDR parallels the new EU medical device regulation (MDR [26]) and was also issued on May 26, 2017. In contrast to the MDR, which became effective on May 26, 2021, the official date for its starting validity is May 26, 2022.

Therapies with medical devices are directly linked to quality and outcome of patient care and thus, determine QoL. The portfolio of medical devices also includes healthcare budgets and profitability for medical device manufacturers (Fig. 10.6).

Medical devices can be considered the motor in many therapeutical interventions. In order to be innovative and cost efficient, developments in medical technology undergo a long-lasting process from concept, production and approval to marketing and clinical application. By collaborative interactions and commitments between the many involved stakeholders, priority needs within regulated areas and points of intersections have to be defined to address benefits. *Design thinking* approaches start here and could support the enhancement of innovation, efficiency and reliability in medical device technology [24]. From a manufacturer's point of view, the three "G's" play a major role, and have to be practiced:

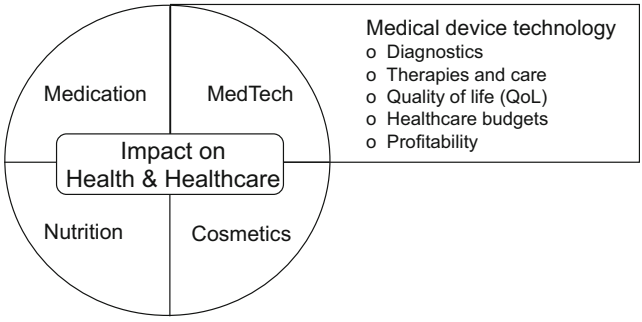

Fig. 10.6 Health and healthcare are influenced by many key players, such as medication, nutrition, cosmetics and treatments with medical devices. Apart from direct interactions with patients in terms of diagnostics, therapies and QoL, the portfolio of medical devices also impacts healthcare budgets for health insurance funds and the profitability of manufacturers

- **G**ood Manufacturing Practice (GMP),
- **G**ood Laboratory practice (GLP) and
- **G**ood Clinical Practice (GCP).

See also Chap. 13 for details on GMP, GLP and GCP. In addition, medical devices can only be marketed when they have been approved by authorities, such as e.g. EMA (Europe), FDA (USA) or MHW (Japan) after having undergone successful clinical trials from Phase I to IV. It is understandable that these processes need time and money.

As compared to clinical therapies and related P4P programs, two aspects determine investment and innovation in the medical device field: Compliance and Cost.

Compliance refers to established standards and regulations, such as e.g. the EU Medical Device Regulation MDR (which came into force on May 26, 2021, [26]), the in vitro Diagnostics Regulation (MDR/IVDR [25]), the ISO 10993 (Biological evaluation of medical devices), the ISO 14971 (Application of risk management to medical devices [27]), and Regulation (EC) 1394/2007 on Advanced Therapy Medicinal Products (ATMPs [28]) or others. Most of them are touched in detail in Chaps. 4, 5 and 13.

Cost and investments for research, production and marketing determine competitiveness of medical device manufacturers in a global market. Both terms, compliance and cost, are addressed in two statements with a similar sentence construction.

Already in 1957, Mary Lasker (1900–1994), an American healthcare activist and founder of the "Lasker-Award for Medical Research and Technology", commented concerns about necessary high cost for investments in innovative medicines [29]:

If you think research is expensive, try disease!

Thinking in a similar way, the former U.S. Deputy Attorney General Paul McNulty addressed compliance in 2009 [30]:

If you think compliance is expensive, try non-compliance!

International regulatory affairs, as well as prescriptions to perform quality- and risk-management processes, are costly and affect economic growth and the competitive position of medical device manufacturers. The return-on-investment (ROI) of globally active medical device producers further depends on national regulations, incentives and subventions for medical devices and related therapies and are thus, uncontrollable by a manufacturer. As shown e.g. for the treatment of chronic kidney failure, the reimbursement of thrice-weekly haemodialysis, including cost for medical devices, strongly depends on national variables (Table 10.1, [31]).

Budgets in healthcare depend on their availability. Current global trends tend to budget restrictions despite the increase in the number of patients in need. However, some financial resources for healthcare and medical devices are still for things without value. Analyses from the USA attest that a high amount of money and budgets in healthcare are spend on nothing due to system failures (Table 10.2, [32, 33]. The authors of these analyses, W. Shrank and colleagues, also reviewed the available literature on efforts to reduce wasted money and concluded that about

Table 10.1 Reimbursement per thrice-weekly haemodialysis services in different countries (in US-$)

	Belgium	Germany	The Netherlands	United Kingdom	France	US–Ontario	Canada
Self-care haemodialysis	1045	675	1668	744	909	689	502
Home haemodialysis	1045	675	1246/1905	744	816	689	385
CAPD	985	1077	1126	502	718	689	636
APD	985	1077	1126	612	925	689	733
Hospital haemodialysis	1608	675–1131	1668	744	1364	689	745

Data taken and compiled from [31], CAPD - Continuous Ambulatory Peritoneal Dialysis, APD - Automated Peritoneal Dialysis

Table 10.2 Identified six domains showing a high range of wasted annual money in healthcare in the United States of America.

Wasted money [in billion US $]	Reason	Value of savings from interventions [in billion US $]
104.2–165.7	Failure of care delivery	44.4–93.3
27.2–78.2	Failure of care coordination	29.6–38.2
75.7–101.2	Overtreatment or low value of care	12.8–28.6
230.7–240.5	Failure of pricing	81.4–91.2
58.5–83.9	Fraud or abuse	22.8–30.8
265.6	Administration complexity	n.a.
760–935	Annual cost of waste (25% of total US healthcare spending)	
	Savings from interventions	191–282

Data compiled from [33], *n.a.* not assessed

25% of these expenditures could be reduced with the implementation of well documented current programs. According to an analysis of the US Institute of Medicine interventions, which have proven to be of value in healthcare, such programs need unfortunately 15–17 years until they penetrate general use in the healthcare environment. Whether these figures from the USA are representative for other countries either, still remains a matter of debate.

The question arises on how these cost considerations can be put into positive perspectives and how financial and hardware resources for medical devices can be exploited more efficiently. The look on general conditions of medical device- and healthcare providers and related markets may offer a closer understanding of the current situation (Fig. 10.7).

The medical device market has become global. The export of devices and related systems determines production, marketing and sales and last but not least also foreign investments. Manufacturers profit from practical clinical applications of

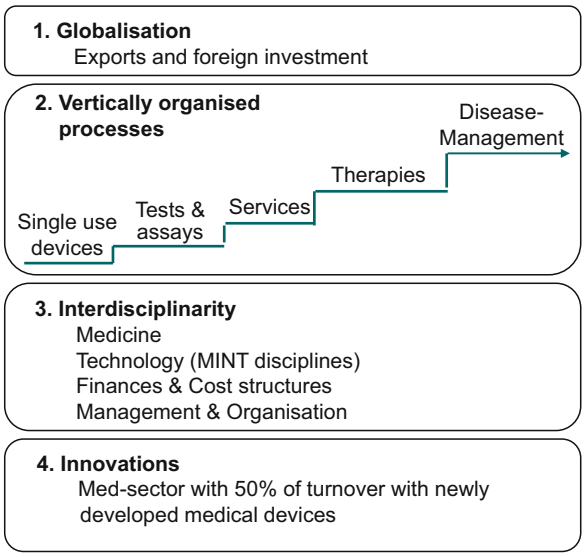

Fig. 10.7 Current situation and boundary conditions of modern medical device industries

medical devices based on intense scientific investigations, which are performed both in-house and in collaboration with academic institutions. As a consequence, the production of medical devices is subject to a "systems approach", which includes vertically organised processes from in-house production to extramural clinical application. Cost considerations and performance assessments are key figures here. For instance, concepts to abandon reuse of devices and supply instead single use items have been advanced in order to achieve safety and guarantee performance during the device's shelf-life time. The use of reliable in vitro test systems to guarantee high device quality prior to clinical application, the involvement of devices into the delivery of services and their application in both ambulant and clinical therapies under the supervision of a disease management represent further steps in such vertically organised processes (Fig. 10.7).

The medical device industry further needs employees with an interdisciplinary background. Medical devices, once developed, cannot be further developed and sold like commodity products. Only employees with curiosity and knowledge in scientific disciplines, such as natural sciences, engineering, finances and—not to forget—ethics are a *conditio-sine-qua-non* for successful innovations and subsequent success in healthcare. The huge number of 10,480 granted European patents in 2020 [34] provides evidence that MedTech has become one of the most successful engineering realms.

The performance of medical devices during therapeutical interventions and diagnoses depends on heterogeneous clinical targets. In other words, a "one-fits-all" device does not exist. For instance, an integrated performance of different functionalities of medical devices will be necessary, given that the expected increasing use of telehealth technology will come true (Fig. 10.8). Sensors for physiological

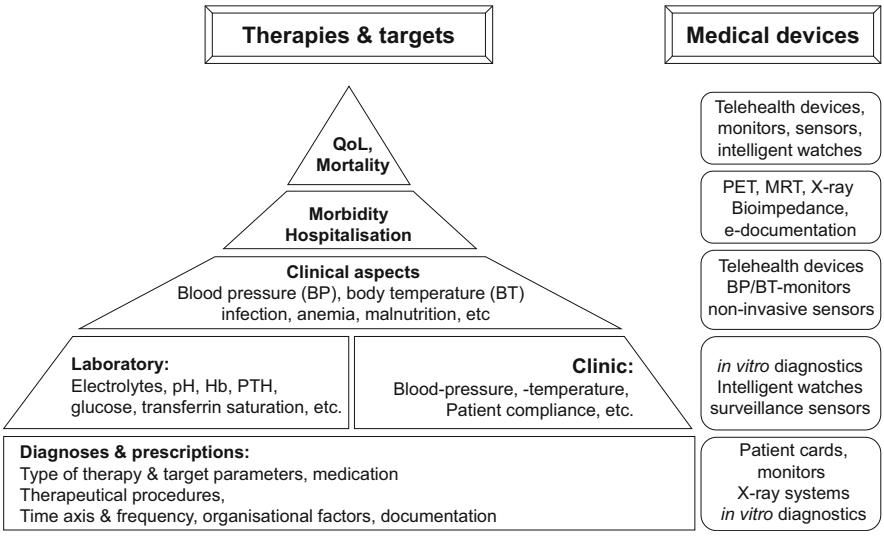

Fig. 10.8 Scheme of therapeutical and analytical interventions in healthcare services supplemented by some examples of related medical devices. Based on the expected increasing use of integrated performance of medical devices, telehealth allows for new device opportunities in terms of a systems approach

parameters, both invasive and noninvasive, combined with broadcasting- and documentation-systems are models for such a systems approach in Medical Technology.

It's not surprising, that the required performances and needs for quality and reproducibility of medical devices (MDs) has led to the availability of more than 400,000 different types of medical devices and in vitro diagnostics on the European Market in 2017 [35]. A general scheme for the use of MD's aims, targets and types of devices is shown in Fig. 10.8. In addition, the need for sophisticated complex medical devices expands, when medical knowledge increases and clinical interventions are performed under conditions of evidence-based medicine. Taken together, the medical device industry is exposed to big challenges, not to keep only their shareholders satisfied. These challenges can be described by the following five "P's":

- **P**roduct: A MD should be marketable in global markets.
- **P**otential: A MD should be able to be used synergistically with other MDs.
- **P**erformance: A MD should perform well under all environmental conditions.
- **P**rofit: A MD should allow for a considerable return-on investment (ROI).
- **P**erspectives: A MD should also allow for establishing a platform technology.

10.2.2 Innovative Products for the Reduction of Total Cost of Care

An ideal example to prove the potential of innovative medical devices can be taken from haemodialysis (HD), a therapy for the treatment of chronic kidney patients. It is based on an extracorporeal blood circuit which allows for purifying blood from uremic retention solutes. Patients suffering from end-stage kidney disease have to undergo an HD-therapy three times a week for the rest of their lives, if no organ transplant is available as an alternative. In 2019, a global number of 4,370,000 patients suffer from end-stage kidney disease (ESRD), 3,160,000 thereof are treated by haemodialysis, 393,000 by peritoneal dialysis and 817,000 have received a kidney graft [36]. Medical devices used for HD are usually composed of disposable syringes, tubing, filters and sensors. With the help of dialysis machines (monitors), the treatment is realised and continuously controlled. Treatment parameters are automatically documented with the help of a software which is part of the dialysis monitor and stored on a patient card. This enables nephrologists to compare treatment performances between two dialyses of an individual patient or even between different patients.

In order to guarantee safety and security against infections and cross contaminations with viruses between neighbouring patients in a dialysis centre, single use devices have been preferred compared to reused devices. Haemodialysis represents a chronic therapy with a repeated thrice-weekly use of medical devices for many years. Given that the global 3,1 million HD-patients are treated with single use devices, a weekly supply of around 10 million sets (syringes, tubing, filters) is needed. Therefore, the timely supply, reproducible performance and quality of these devices must always be under control and the clinical success of treatments be followed.

Therapy providers or physicians, who run dialysis centres, are responsible for disease management, which includes responsibilities for the individual therapy, for devices and their actual performance as well as for the availability of a functioning medical device item (Fig. 10.9a).

The average cost for haemodialysis treatments in the Western hemisphere adds up to about >65,000 € per patient and year and are to be covered by health insurance funds or healthcare budgets. However, many countries without health insurance exist, such that kidney patients remain untreated. Initiatives are currently underway to achieve cost reduction by establishing a close control of both medical device performance and treatment efficiency (Fig. 10.9b).

With innovative medical devices in haemodialysis, therapy control and responsibility can be delegated to and adopted (at least in part) by medical devices. Noninvasive sensors (with focus on "noninvasive") for blood temperature [37], blood volume [38] and body composition (water, fat, muscle mass) [39, 40], pulse-rate, pulse wave velocity [41], online clearance measurement of filters [42], closed loop lung ventilation [43], glucose analyses [44] and others, are capable to continuously assess and control physiological parameters of a patient. When applied as a closed loop and linked to the dialysis monitor, treatment conditions can be acutely modified and adapted depending on the patient's performance.

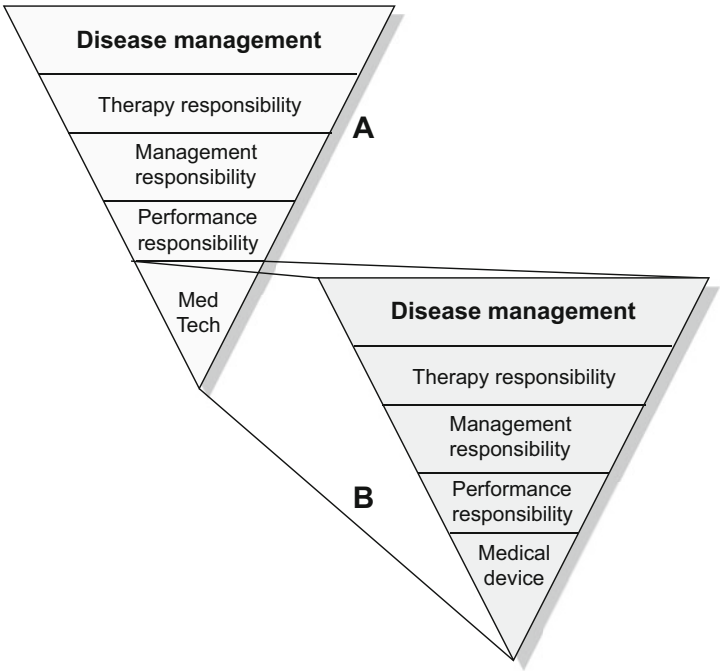

Fig. 10.9 Therapy providers or physicians, who run dialysis centres, are responsible for disease management. It includes responsibilities for the individual therapy, for the correct use of sterile medical devices and their actual performance, not to forget the availability of functioning therapy systems (**a**). With innovative medical devices, therapy control and responsibility in haemodialysis can be delegated to and adopted (at least in part) by medical devices (**b**). Cost savings are supposed to be realised then

Data and figures obtained by these feedback controls are currently collected and incorporated in global big data banks [45]. They allow for detailed analyses of different patient cohorts, their clinical performance and QoL. As a result, therapies can be adapted to an acutely changing patient condition and treatment modes optimised. With the help of this device technology and the future combination with tools of artificial intelligence a continuous monitoring of long-term patient behaviour and treatment quality can be achieved, disease management technically realised and last-but-not least cost of care reduced (Fig. 10.9b).

10.2.3 Adaptation to Different Requirements of International Healthcare Systems by Innovative Processes

Four out of five MedTech companies have either changed their business model in the past 3 years or are currently considering changing it. Reasons for this observation are changes in macrotrends, such as

- Cuts in healthcare spending
- Decline of investments on prevention of disease
- Focus on patient-centric approaches
- Value *vs*. volume considerations

How to cope with these findings and still provide a profitable business for Healthcare Provider Organisations (HPOs)? Budgets of healthcare systems may suffer from wasted resources. Obviously professional managerial skills are needed to improve the exploitation of financial resources. One solution might be to reduce the number of involved stakeholders and keep responsibility and management of resources for healthcare in one hand or in one company. This leads to the foundation of *vertically structured* companies, who control the entire business-to-consumer chain. The realm of haemodialysis offers such opportunities, when a company provides goods and services for patients and is simultaneously able to run dialysis clinics and centres. A considerable asset of such companies is based on applied research on polymers and on instruments for dialytic therapies, the production of medical devices and their adaptation to medical needs through the realisation of clinical trials. By this means, clinically derived documents can be timely submitted for approval processes and investigations on specificities of global markets can be performed in-house. Manufacturing all necessary products for dialysis therapy in one hand and running dialysis clinics for their application on the other hand will allow for a worldwide recognised high quality of medical devices, as well as for therapy standards. For instance, the highly efficient treatment mode of hemodiafiltration, promoted by the globally active company Fresenius Medical Care has shown to lead to an improved survival of dialysis patients and a better perceived QoL [46].

With the increasing global number of dialysis patients, manufacturers tended to increase their production capacity of medical disposables in order to profit from the "economy of scale". This allows them to offer medical goods cheaper and thus becoming more competitive. This actual "volume-driven" model, however, is under pressure, when Healthcare Provider Organisations (HPOs) modify their mission statement and focus more on value-based businesses. They undergo a metamorphosis and change from a classical device producer to a therapy provider whilst keeping all necessary activities in one hand. Disease management has become the magic word, which has now opened new ways for HPOs.

Innovative managerial processes dedicated to vertical integration have turned out to be one reason for this new way to success. A close link to international global customers and thorough analyses of markets and needs has further led to a better understanding of different healthcare cultures. Through combining sectors of opportunities for cost reduction, such as in sales, by bundle and care contracts, as well as services with focus on disease management, customer and market needs could be recognized and an optimal use of financial resources obtained (Fig. 10.10). "Medical device innovation— ***is better good enough***?" asks the New England Journal of Medicine in its editorial in 2011 [47] and proposes a model-based approach for the improvement of medical device technology and its evaluation by well documented

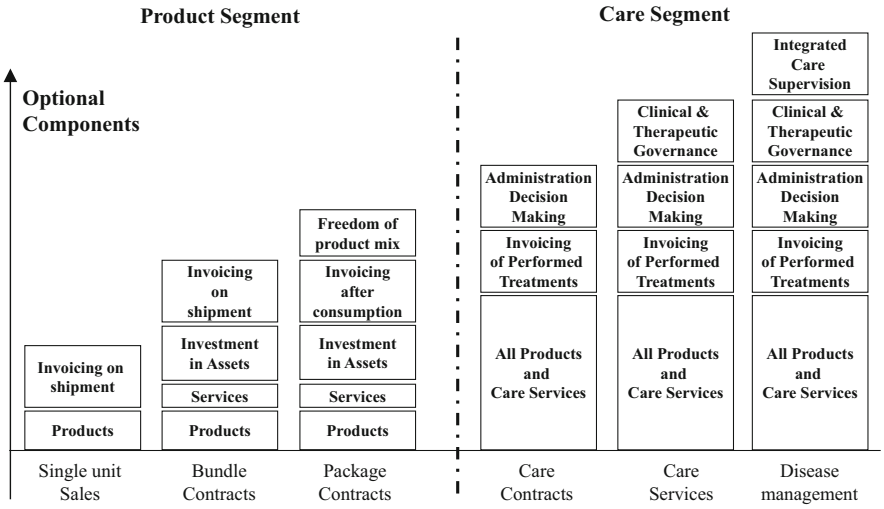

Fig. 10.10 A healthcare system is based on value related to two segments, products and care delivery. The concept of vertically integrated companies in MedTech bases on combining these segments in order to cope with both the needs of customers (patients) in international markets and payers under a single-handed control. The sequential steps until its final stage are shown here with the final result in the right-hand column. This model covers aspects from "device sales", bundle contracts for the delivery of all necessary medical devices, care contracts with hospitals, care services to "disease management". It allows for a better exploitation of financial resources and a higher return-on-investment (ROI) for the respected company

clinical applications. Vertically integrated companies may be the optimal model to cope best with the challenges in the medical device field.

Conclusion

Demographic changes, limited healthcare budgets and performance-based attitudes for medical therapies have led to Pay-for-performance programs in healthcare. Here, consumer (patient), provider (physicians and nursing staff) and payer (patient and health insurance funds) are all involved. To reach targets based on measurable quality indicators, incentives are provided for the efficient use of medical resources and medical devices. The establishment of such key factors needs a consensus among the involved stakeholders to be successful. This consensus can only be reached if the interests of these groups are balanced, beard in mind and special attention is paid to a complex process. Artificial intelligence-based analyses of large patient data bases may be of help in improving this situation. Medical devices underwent a metamorphosis from a simple instrument to a complex tool allowing for sophisticated performances and the active, online interaction with treatment modalities. Innovative devices allow for covering preventively responsibilities in medical care and impact disease management. Vertically structured companies can serve as a model for successful corporates in medical device technology.

Take Home Message

- Demographic changes, limited healthcare budgets and performance-based attitudes for medical therapies have led to Pay-for-performance programs in healthcare.
- Pay-for-performance programs in healthcare are able to increase perceived Quality of Life (QoL) in patients but are not successful in reaching the desired endpoint of a lower mortality.
- Artificial intelligence-based analyses of large patient data may be of help in improving this situation.
- Medical devices underwent a metamorphosis from a simple instrument to a complex tool allowing for the active and online interaction with treatment modalities to achieve patient-specific improvements of care.
- The performance of medical devices has reached a higher level of perfection through a "systems approach" which bears in mind a synergistic action of all involved devices and actors.
- Innovative devices allow for covering preventive responsibilities in medical care.
- Vertically structured companies are the model for successful corporates in healthcare.

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