Disease management programmes: reorganization of healthcare delivery in Germany

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Since 1 July 2002, a legal basis has existed for the drawing up of contracts between physicians and health insurance companies, allowing for the structured treatment of diseases [disease management programmes (DMPs)] for common and economically relevant diseases [1]. DMPs give structured directives to the physician on how to deal with defined medical situations and provide minimum standards for target parameters. Such diagnostic and therapeutic procedures should be developed from evidence-based data and guidelines without limiting the clinical freedom of the physician. DMPs are intended to standardize medical practice and make it measurable, similar to that intended for diagnosis-related groups, the systems adopted to measure items in hospital care. The ultimate aim is to promote competition between healthcare providers and to make medicine more economical. The first two diseases selected for this purpose were type 2 diabetes mellitus and carcinoma of the breast, to be followed by chronic obstructive pulmonary disease, coronary heart disease and others.

These medical problems are prevalent in all European countries and apart from healthcare considerations, there are other factors, i.e. demographic developments and medical innovation, that cause progressive increases in healthcare costs. Since the European Union abolished limitations of residence for physicians and introduced standards for medical training and professional work in directive 93/16/EEC in 1993 [2], these developments in Germany are certainly of interest throughout the European Union. Today it is possible to 'purchase' medical care from across the borders and this is widely practised in regions close to the border. The Europe-wide discussion on DMPs is necessary, since these touch not only on healthcare economy, but also affect the way physicians perceive their own role.

Conflict of interests concerning diabetes type 2

The selection of diabetes type 2 as the first item for DMP was reasonable because it is an economically relevant disease. The prevalence will increase from currently 6% to 10% in the near future and costs for complications, such as amputations, coronary care, blindness and dialysis, are immense. Apart from general considerations to improve the health of the population by such programmes, it is anticipated that early diagnosis and treatment will reduce costs. It goes without saying, however, that at the outset the introduction of such programmes will lead to the discovery of undiagnosed patients and temporarily cause additional expenses.

Apart from healthcare expenses per se, general economic aspects play a great role in Germany, because health costs are added to wage costs and, thus, increase the overall cost of the work force. As a result, the federal government tries to reduce total health costs, although many physicians feel that there is no alternative to a fundamental reorganization of the healthcare system.

There are more than 300 legal health insurance companies in Germany. Recently they have started to compete with each other for members, which has forced them to reduce costs. To protect legal health insurance companies against fixed costs from cost-intensive patients, a mechanism called ‘Risikostrukturausgleich’ (equalization of risks) was introduced in 1994. DMPs are simply an instrument with which to implement such ‘Risikostrukturausgleich’. As a result, legal health insurance companies must be interested in recruiting for the DMP those patients most likely to qualify as high-risk patients, but who nevertheless require few expenses (in the ideal situation ‘healthy type 2 diabetics’).

What is the reaction of physicians to this programme? On the one hand, physicians are concerned that the freedom to select individualized treatment is in danger. On the other, they are afraid that the relation between physician and patient will be
strained because sensitive data are disclosed to the legal health insurance companies. Finally, there is concern that the economic and social status of physicians will be jeopardized by becoming more dependent on the legal insurance companies.

In Germany, the patients themselves are used to a socially balanced system of medicine which is very congenial to the patient, as he is not forced to concern himself with costs (apart recently from contributing to part of the cost of medication).

The legal situation after introduction of the new law

Intention

The foreword to the fourth law changing the ‘Risikostrukturausgleich’ ordinance of 27.06.2002 declares that the aim is improvement of the care of chronically ill patients who are subscribers of the insurance companies. It is intended to provide financial support for such structured treatment programmes without financial consequences for the predicted budget. The proposed solution is to provide standardized procedures for insured members covered by the ‘Risikostrukturausgleich’. This is intended to relieve the financial burden of health insurance companies, who have a high proportion of chronically ill persons. It is intended to create incentives that will reduce cost-intensive inappropriate health-care. The law giver concedes that to carry out the DMPs, additional expenses of unknown magnitude will have to be faced, at least initially, by the health insurance companies.

Preconditions to be fulfilled by a DMP

It is written law that treatment according to the current standard based on scientific principles must be performed according to evidence-based guidelines or the best available evidence. It is necessary to define the goals and individualize targets. It is required that regulations to guarantee quality-oriented and sufficient patient management be respected. In addition, the following conditions must be met.

(i) The diagnosis must be established in accordance with defined criteria.
(ii) Voluntary participation of the patient must be ensured.
(iii) Patient data must be made available to the insurance companies (‘... to support the care of the insured member ... enabling them to recognize a situation whereby the patient’s failure to cooperate would disqualify that patient from participation in the programme ...’).
(iv) Education must be provided to patients and physicians.
(v) Adequate documentation must be provided.
(vi) Outside evaluation must be allowed.

Diagnostic criteria

It will be sufficient to diagnose type 2 diabetes in a symptomatic patient from a fasting plasma glucose of >126 mg/dl or a post-prandial plasma glucose of <200 mg/dl. In symptom-free patients, spontaneous or provoked hyperglycaemia >200 mg/dl must be documented.

Treatment goals

The law states that improvement of hyperglycaemia must be tried. Deliberately, the aimed for blood glucose concentration as well as HbA1c values have not been defined. In the draft of the law as of 21 May 2002, an HbA1c target of 8% was given with the addendum that specific indications might require tighter blood glucose control. To achieve lower glucose concentrations, lifestyle modification and medication on the basis of evidence-based data using insulin (human or porcine), glibenclamide and metformin are prescribed in the text.

In patients with macroangiopathy, the law prescribes normalization of blood glucose, blood pressure and lipids. Hypertension is defined as >140/>90 mmHg. Apart from lifestyle modification, medication using thiazides, β1-selective blockers and angiotensin-converting enzyme inhibitors are prescribed by the law. The choice of lipid-lowering medication is restricted to pravastatin and simvastatin.

In patients with microvascular complications, the law recommends examination to determine whether normal glycaemia is a sensible proposition. Tests for microalbuminuria once yearly are recommended only if diabetic retinopathy has been documented.

Interdisciplinary management

The ordinance prescribes structured cooperation between general practitioners (GPs) and specialists. An ophthalmologist must be contacted once per year and a nephrologist and a diabetologist must be contacted if the patient has retinopathy and microalbuminuria. This is also true when the target blood pressure and HbA1c values are not reached within 6 months of start of treatment. Specialist consultation is obligatory if the patient is pregnant or has a diabetic foot syndrome. Except in emergencies, participating diabetics can be admitted only into suitable hospitals. The only accepted indications are threateningly poor glycaemic control, impaired hypoglycaemic awareness and foot infections.

Execution of DMPs

Health insurance companies have the task of concluding contracts with healthcare providers who must be certified by the Federal Insurance Office (Bundesversicherungsamt) and must be licensed as medical healthcare providers. Only GPs are currently allowed.
Critical evaluation of the programme

Although DMPs addressing diabetes type 2 have existed since 1 July 2002, no functioning programme has been established since November 2002, because of a time-consuming, in depth discussion between the different institutions, e.g. the cooperation of private physicians (Kassenärztliche Bundesvereinigung, regionale Kassenärztliche Vereinigung), medical boards representing all physicians (Ärztekammern), medical specialists associations (German Diabetes Society, professional cooperatives of GPs and internists) as well as the different health insurance companies.

Physicians do not deny some positive aspects. It is admitted that this legislation has formulated an important principle, i.e. that the qualitatively best findings of clinical research should be the basis for diagnostic and therapeutic decisions. This may be complemented by the personal clinical experience of the physician and the personal view of the patient. The integration of guidelines into the treatment provided by the physician allows for the quality control of such treatment. The planning of educational programmes and continuing interdisciplinary treatment of chronically ill patients are also considered to be positive aspects [3].

On the other hand, however, serious critiques prevail. The medical cooperatives consider the programme not well thought out or matured. They criticize the link between the medical goal and economic as well as political goals. They are concerned that the special relationship of trust between physicians and patients will be jeopardized by making information accessible to third parties. There is also criticism of the fact that physicians' freedom to choose therapies will be unduly restricted. Finally, there is concern about the amount of money and resources wasted on administration.

The German Diabetes Society and other specialist societies criticize the fact that innovative strategies are not considered in the DMPs. It is feared that this will lead to regressive medicine and obsolete treatment principles. They also criticize the link between DMPs and the Risikostrukturausgleich (risk equalization programme), i.e. with the goal to reduce costs. There is concern that standards of medical care will be lowered. It is finally criticized that the quality of care in the guidelines is considerably lower than the national guidelines of the German Diabetes Society.

‘Individualization or standardization in medicine’ was the central topic at the annual meeting of the cooperative of German physicians (Ärztetag) in Rostock 2002. It was acknowledged that rational treatment based on evidence and directed by guidelines is reasonable in principle. Concerning DMPs, it was postulated that medical data can be made available to third parties, including health insurance companies, only without specifying the person involved. It was also postulated that the physician must have the option to introduce treatments that are not listed in the ordinance. It was criticized that in-patient care was not part of the DMP and that DMPs are used for financial manoeuvres in Risikostrukturausgleich, so that chronically ill persons are used as political pawns.

The annual congress of the German Diabetes Society in Dresden 2002 decided on the following goals, formulated by the President, for the treatment of patients with diabetes mellitus type 2 [5–7].

(a) Improvement of the quality of care within stable costs.
(b) Structured intervention instead of therapy for symptoms.
(c) Active involvement of well-educated and trained patients.
(d) Treatment by the physician according to evidence-based guidelines.
(e) Preventive instead of reparative medicine.
(f) Integrated patient care.
(g) Quality management and development of quality standards.

The medical profession in the future

There is undoubtedly interdependence between the medical profession and the development of society. The euphoria of scientific medicine in the 20th century, that everything is possible, will be limited by social and financial restrictions. This is bound to alter the way physicians see their own role, because their performance can now be measured and compared.

The new ordinance refers openly to faulty developments in the provision of medical care. One federal insurance company [4] openly campaigns for ‘a new way of thinking for physicians’, confronts paternalistic in opposition to patient-oriented medicine and guideline-based care against classical therapy as well as team playing against hero worship in the relation between physicians and patients.

We come to the conclusion that improved treatment of common chronic diseases, such as diabetes mellitus and coronary heart disease, are necessary, not only from the perspective of patient care, but also because of constraints imposed by national economics. DMPs, in principle, could be a suitable instrument to reach this goal. Physicians in Europe, not only in Germany, must be aware of the fact that DMPs will lead to fundamental changes in medical practice. Because of the professional competence of physicians and in order to preserve the sensitive relation between physician and patients, case management and data control must remain in the hands of physicians.

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Conflict of interest statement. None declared.

References

1. Vierte Verordnung zur Änderung der Risikostrukturausgleichsverordnung: Bundesgesetzblatt 27.06.2002

Editor’s note

With progressive harmonization of European health policies, developments in one country are of interest to physicians in all European countries. It was with this in mind that the editorial office felt it useful to keep clinical nephrologists in Europe informed about recent developments in Germany.