CORRESPONDENCE

The Benefit and Efficiency of the Disease Management Program for Type 2 Diabetes

by Prof. Dr. med. Roland Linder, Dr. rer. medic. Susanne Ahrens, Dagmar Köppel, Thomas Heilmann, Dr. rer. nat. Frank Verheyen in volume 10/2011

Quo Vadis, Techniker Krankenkasse?

In January, the Techniker Krankenkasse (TK, a statutory health insurance fund in Germany), in collaboration with the Verband der Ersatzkassen (association of substitute health insurance schemes) and the statutory health insurer for North-Rhine (Kassenärztliche Vereinigung Nordrhein, KV) issued a joint press statement regarding the high quality of the disease management programs (DMP) in North-Rhine and the ensuing benefits for patients.

Now, an original research article appears, "The Benefit and Efficiency of the Disease Management Program for Type 2 Diabetes," which was submitted to *Deutsches Ärzteblatt* on 29 July 2010 and published in the issue of 11 March 2011. The article's key message is that the study does not reveal any clear medical benefit from DMP participation.

Closer reading of this original article reveals multiple inconsistencies that substantially limit the meaningfulness of the article. What would make sense is a prospective analysis over several years or even decades, and not a retrospective analysis over two years (2007/2008). The inclusion criterion of registering a patient for a further DMP also throws up questions.

In addition to so called hard end points, data on newly occurring typical comorbidities were collected and treatment successes in terms of adhering to standard values were used for the assessment.

With regard to this the observation period is insufficiently long and using adherence to normal values is a pointless reflection of surrogate parameters. Hard end points regarding mortality over a long observational period would be required in this setting.

Although, as the authors themselves cite, the statistical tests (Chi square test and Mann-Whitney U test) are not valid in their application after the so called matching, they were still used to assess the results.

The point and purpose of this publication remains speculative and does not seem to serve any medical benefit. If the TK were systematic in its approach, it would have to cancel its participation in the DMP for type 2 diabetes (T2DM), but it might lose face in the eyes of the insurance scheme members by cutting preventive healthcare services..

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Incidence Has Fallen

The authors regard the incidence of foot amputations (OPS code 5–865) as an efficiency criterion for T2DM (1). However, OPS code 5–865 entails amputations of parts of the foot, e.g. of single toes (minor amputations), which do not always lead to serious impairment or necessitate a prosthesis. By contrast, the crucial criterion is saving the leg and, thus, OPS code 5–864 (leg amputations). Whenever leg-saving measures are applied successfully in cases of gangrene of a foot, only minor amputations instead of leg amputations are required. If accompanied by a low incidence of major amputations (OPS code 5–864), a high incidence of minor amputations (OPS code 5–865) could therefore point to a high efficiency of the management program. Since the start of the DMP for type 2 diabetes, the incidence of leg amputations in all members of the general statuary sickness fund (AOK) of Westphalia-Lippe has decreased successively from 46/100 000 in 2000 to 26/100 000 in 2008 (while the incidence of amputations below the ankle has increased; personal communication). What is the incidence of leg amputations in the groups of T2DM patients studied by Linder et al. (1)?

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Sponsor Bias

Disease management programs (DMPs) are complex interventions, and, like all medical interventions, they

should undergo adequate scientific evaluation before being widely implemented into healthcare services, in order to find out their positive and negative effects and bear these in mind when treating patients. As the patients who are accepted into a DMP differ from those who cannot participate in these programs for whatever reason owing to legal regulations alone, a reliable evaluation of the DMP effects can be done only by means of a prospective randomized controlled trial (RCT). Unfortunately, and in spite of existing concepts and study protocols, it was not possible for those responsible to shape the introduction of DMPs in 2002 in such a way that they were accompanied by such a valid evaluation. Linder et al attempt to use the methodological concept of the propensity score approach in order to describe the effects of the T2DM (1). In this, they were unsuccessful because the comparison parameters are not fairly distributed between the intervention group and the control group. The method of retrospective control group formation is subject to the so called sponsor bias, in which the results of a study are distorted, consciously or unconsciously, into the direction desired by the sponsor (2). Since a prospective evaluation of DMPs in the setting of an RCT is unlikely, future evaluations of DMPs will also have to apply methods that are prone to distortion. In order to minimize "sponsor bias," such evaluations should be organized jointly by health insurers that are interested in a "positive" result and health insurers that are interested in a "negative result" and conducted by an independent body.

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Professor Sawicki was involved in the development of the T2DM and in setting out the RCT study protocol.

Collective Was not Representative

Linder et al compared TK insurance members who were registered in the T2DM with those who were not. Because of similar findings in both groups they conclude that the T2DM is not effective, inefficient, and does not make sense in its current form. This cannot be deduced from what they described in their article. Critiquing individual methodological details would take up too much space here. Other types of sickness funds reached reverse conclusions using comparable methods (Stock et al, 2010).

Linder et al criticized that the DMP quality report of the statutory health insurance in North-Rhine did not evaluate the programs appropriately. On the basis of this report, however, it is possible to show in a transparent and detailed fashion the extent to which those registered with the DMP in the region actually reached the objectives set for them. The analogous criticism of the ELSID study is not justified because ELSID is currently the methodologically most complex, prospective, control group-based study of the medical effectiveness, health related costs, and quality of life in patients with type 2 diabetes in Germany.

Whether the TK study is representative for the entire collective of patients with type 2 diabetes seems questionable on the basis of the experiences gathered in North-Rhine. According to these, TK insurance members are younger than the average of all participants registered in the T2DM and mainly male; during their participation in the T2DM they developed fewer complications and continually showed better metabolic and blood pressure control than all other registered diabetes patients.

In order to make robust, generalizable statements, it would therefore be necessary to:

- Match TK insurance members with non-TK insurance members regarding their specific characteristics and baseline status,
- Extend the observation period beyond the study timeframe (here, a maximum of two years was considered), and
- Document numerically the frequency of individual end points, as well as outpatient and inpatient costs in additional tables.

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The DMP project office undertakes certain tasks for the purposes of quality assurance for the DMP in North Rhine-Westphalia, on behalf of the Association of Statutory Health Insurance Physicians in North Rhine-Westphalia and the association of hospitals (Krankenhausgesellschaft) NRW.

Matching Should Take Place Before the Start of the Study

Linder et al criticize the evaluation of DMPs in Germany and present their own study (1). Their study has methodological limitations that put in question the validity of their results. Firstly, we wish to point out the incomprehensible formation of groups. Matching has to be done before starting an intervention. In the Linder et al study, patients registered before 2007 were not excluded, however, and paired in 2006, which already partly eliminates the effect of the intervention. What is not clear either is why the researchers did not pair each DMP participant with a control from the sufficiently large pool. Patients who participated in more than one DMP were also excluded. This means that seriously ill people were excluded who would have benefited particularly from an improved healthcare structure. Patients who were registered very recently were included, in whom no effect has had time to manifest. Furthermore we cannot follow how subjects can be paired according to the variable "Education", if pertinent data were lacking in almost 70% of identified diabetes patients. It is not permissible to use "missing" as a valid pairing variable. The authors have therefore missed their own objective, namely that of considering more carefully selection effects in evaluating the DMPs.

A study published in December 2010 that showed a positive trend in the quality of care and efficiency in participants in the DMP diabetes compared with a group of non-registered diabetes patients was not discussed (2). This is surprising as this was the first study in Germany that evaluated the T2DM by means of propensity score matching.

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An Unbiased Approach Is Necessary

Linder et al claim to mostly have ruled out selection biases by means of an "sophisticated control group design." However, in order to do so one would have to approach the study subject in an unbiased fashion, otherwise even methods such as the described "propensity score matching" entail the risk that the inappropriate or incomplete patient selection criteria, which affect the model, determine the results. Against this background, readers might ask themselves why relevant comorbidities such as coronary heart diseases and arterial hypertension were not considered, or why with regard to myocardial infarction, only ICD-I21 was included, but not other relevant diagnoses. The question also needs to be asked why patients should be included in such an analysis who were registered in the T2DM for only one or a few quarters. Which effects should one expect if patients were enrolled to the dMP only for a short time? It is completely incorrect to state that the ELSID study, which is being conducted by our working group, has a "inadequate" control group design and does "not fulfill the requirements of a scientifically based study." This is a strong statement regarding a project that in its evaluation—in contrast to Linder et al—considers overall morbidity in matching rather more comprehensively and ensures a sufficiently lengthy registration period before drawing conclusions about effectiveness. Although further development of the T2DM is needed in some aspects (for example, in order to focus on high risk patients) and improvements to its implementation are necessary, there are now many study results that show improved healthcare provision (1) and a higher degree of activation of the patients (2). This seems to benefit in particular older and multimorbid diabetes patients—exactly those patients who constitute the majority of those affected. Not to mention the important impulse that the DMPs provide for practice teams (especially doctors and other medical professionals) to further professionalize their dealings with chronically ill patients and to further develop internal practice structures (3).

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The author has been reimbursed for conference participation and has received travel expenses from the Federal Association of the general local sickness funds [AOK].

In Reply:

During the introduction period of the DMP, an opportunity was missed to generate the best possible evidence by means of a prospective randomized controlled trial (RCT) before the DMP was widely implemented. It therefore remains an ongoing challenge to support the best possible evidence by means of studies. In spite of all methodological hurdles it would now still be possible to set up an RCT. As a complementary measure, additional data sources—such as data from the sickness funds—could be used for the purposes of evaluation. Using the available funds efficiently in the statutory sickness funds requires comprehensive and valid evaluation of the DMP, in order to modify these programs in such a way that the optimum cost-benefit relation can be achieved. It is therefore essential to demand that the funding used for the DMPs, of more than 1.1 billion Euros per year, have a tangible effect for those affected.

Drabik et al mention the 1:1 matching used in the study published by Stock et al (1). According to our own benchmarking, the selection of the matching method has a negligible effect in the present study. Excluding insurance members participating in more than one DMPs served the purpose of studying a population that can be defined as clearly as possible. The relevant selection effects explained by Drabik et al are much more pronounced in the study reported by Stock et al, which included only those diabetes patients with at least three prescriptions of antidiabetes drugs in 2002. Because—as Stock et al themselves explain—25–30% (according to our own investigations: 39%) of diabetes patients do not take pharmacotherapy, mildly ill patients are not considered in the study and the effect of the DMP is therefore overestimated. A similar effect results from excluding patients younger than 40 and those who changed sickness funds, who were as a rule less severely ill. The result is a subgroup with more than 40% of diabetes patients, who are mostly severely ill. This is a non-permissible subgroup formation when one considers whether the currently practiced watering can principle in DMP registration makes any sense at all. It also explains why—as Altenhofen et al say in their letter—different sickness funds with comparable methodologies reach diametrically opposite conclusions. However, we share the insight that especially a subgroup of severely ill diabetes patients benefits from the DMP, which is also the result of the subgroup analysis conducted by the WINEG.

Szecsenyi calls for taking further comorbidities into consideration, Chantelau for including leg amputations, but objective selection criteria are lacking. Including further parameters can risk the matching in as far as it relativizes the influence of undoubtedly important influential variables. It was not possible for us to consider the study reported by Stock et al that Drabik et al mention in their letter as it was published only after our own study had been submitted for publication. Heinsch in his letter points out the noticeable, growing importance of the DMP in North-Rhine (2) on the basis of documentation sheets. This does not contradict the WINEG study, because the general quality of medical care for diabetes patients has improved simultaneously (3). The quality reports can thus not provide proof of causality. Heinsch rejects the evaluation of surrogate parameters and asks for hard end points instead. This is exactly the approach taken in the WINEG study. Mortality as the hardest end point was not investigated in the WINEG study. The ELSID study (4) concludes that there is no causal association between mortality and DMP registration.

In sum, all evaluations of routine data from the statutory health insurers (which are meant for accounting purposes) are subject to certain limitations. The method suggested by Sawicki to minimize "sponsor bias" is very interesting. At the moment, studies reflect an inconsistent picture. Further studies give rise to the assumption that structured treatment programs do not necessarily lead to cost savings compared with standard treatments (5). It has not been satisfactorily explained either whether the additional costs associated with the DMP are in proportion to their additional effects (6). The healthcare system is challenged to generate valid and reliable data on the cost effectiveness of the DMP.

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The Wissenschaftliches Institut der TK für Nutzen und Effizienz im Gesundheitswesen (Scientific Institute of TK for Benefit and Efficiency in Health Care, WINEG) is tasked to critically appraise the impact of innovations and new programmatic approaches within the statutory health insurers. The authors declare that because of their membership in the TK, a potential conflict of interests exists.