Impact of primary care-based disease management on the health-related quality of life in patients with type 2 diabetes and co-morbidity

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Objective: This study aimed to examine the effectiveness of the German diabetes disease management program (DMP) in patients with varying numbers of other medical conditions with respect to their health-related quality of life (HRQoL).

Research design and methods: A questionnaire, including the HRQoL measure EQ-5D, was mailed to a random sample of 3,546 patients with type 2 diabetes (59.3% female). The EQ-5D score was analyzed by grouping patients according to those on a DMP and those receiving routine care.

Results: The analysis showed that participation in the DMP ($p<0.001$), the number of other conditions ($p<0.001$) and the interaction between DMP and * number of other conditions ($p<0.05$) had a significant impact on the EQ-5D score.

Conclusions: Our findings suggest that the number of other conditions may have a negative impact on the HRQoL of patients with type 2 diabetes. Our results demonstrate that the German DMP for type 2 diabetes may help counterbalance this effect.
Previous research showed that the presence of other medical conditions had a negative impact on health-related quality of life for patients with type 2 diabetes (1-3). In Germany, a special disease management program has been in place throughout the country since 2003, aiming to better structure and coordinate the care of patients with type 2 diabetes. This primary care-based continuous program comprises elements of the Chronic Care Model and is accessible for all patients with type 2 diabetes (4,6). This study aimed to examine the effectiveness of the German diabetes disease management program (DMP) in patients with varying numbers of other medical conditions with respect to their health-related quality of life (HRQoL).

RESEARCH DESIGN AND METHODS
This study was integrated into the ELSID study (2005-2007), a comparative evaluation of the German disease management program for patients with type 2 diabetes. This controlled observational study aims to compare the effectiveness of care provided by DMP with that of routine care (RC). A total of n=20,625 patients were included, of whom 59.2% were female. The sample and the classification of patients in terms of enrollment in a DMP were based on routine claims data (5). The basis for the survey study presented in this paper was a random sample of 3,546 patients (59.3% female) taken from the ELSID population. In 2006, these patients received questionnaires with a cover letter sent by their health insurance provider. Details of the data acquisition have already been published elsewhere (6).

We used the EQ5D, a validated generic instrument for measuring HRQoL, which is available in more than 50 languages. The EQ-5D score ranges from 0 to 1 and can be calculated by applying scores from the EQ-5D preference weights elicited from the general population. For this study, the EQ-5D score was calculated using the value set for the European population (7,8). Further investigations have demonstrated the usefulness of EQ-5D in identifying determinants of health states (9, 10). The minimal important difference for EQ-5D has been reported in the relevant literature as a change in score of at least 0.05 points (11).

The questionnaire comprised questions on sociodemographic characteristics (age, gender, educational level, marital status and household income), self-reported health information (weight, height and smoking status) and a list of conditions other than type 2 diabetes in lay terms (hypertension, osteoarthritis, cancer, previous stroke, coronary heart disease, COPD, asthma, heart failure, previous heart attack and other).

Study protocols of the ELSID study and of this survey were both approved by the ethics committee of the University of Heidelberg.

Statistical analysis: All analyses were conducted with SPSS (version 15.0). The EQ-5D score was analyzed by grouping patients according to those who participate in the German diabetes DMP and patients in RC. To compare the EQ-5D score in both groups, we performed analyses of covariance with DMP (yes/no), the number of other conditions (0, 1, 2, 3, 4, 5, 6 and more) and gender as independent factors and age as a covariate. We considered all main effects and the interaction effect of DMP * number of other conditions. The level of significance was p<0.05.

RESULTS
Of the 3,546 questionnaires mailed, 1,532 were returned (response rate: 42.2%). Valid data were available for 1,399 patients. The EQ-5D score could be calculated for 1,291 patients. A non-responder analysis (on the basis of claims data) showed that responders, compared to non-responders,
were younger, a higher proportion were female and more patients were participating in a DMP.

**Patient characteristics:** Of the 1,399 patients included, 649 were male (46.4%) and 750 were female (53.6%). The mean age for the entire sample was 70.3 (±8.5) years. On average, the patients were enrolled for 26.8 ±9.0 months in the DMP for type 2 diabetes. Significant differences between the two groups did not exist for the whole sample but did for some subgroups. Significant differences were found for patients with no other conditions (age), with one other condition (coronary heart disease, cancer), with two other conditions (previous heart attack), with three other conditions (education), with five other conditions (osteoarthritis) and with six other conditions (heart failure).

The analysis for the number of other conditions revealed that 92.8% of the DMP patients and 93.4% of the patients in RC had one or more other conditions. 70.7% of patients who were enrolled in DMP and 72.9% of patients who were not enrolled had two or more conditions. Moreover, 25.2% of patients in the DMP group and 28.5% in the non-DMP group had four or more other conditions.

**EQ-5D score:** The analysis of the main effects showed that participation in the DMP \( (F_{(1,1276)}=11.50; p<0.001) \), the number of other conditions \( (F_{(6,1276)}=44.35; p<0.001) \), gender \( (F_{(1,1276)}=19.22; p<0.001) \) and age \( (F_{(1,1276)}=14.89; p<0.001) \) had a significant impact on the EQ-5D score. The analysis of the interaction effect (DMP * number of other conditions) also revealed a significant impact on the EQ-5D score \( (F_{(6,1276)}=2.19; p<0.05) \).

An assessment of the estimated EQ-5D score mean values showed that, as the number of other conditions rose, the score decreased in both groups. Starting at 0.826 (CI=0.773-0.879) for DMP patients and 0.790 (CI=0.719-0.862) for patients in routine care with no other conditions, the EQ-5D score decreased for patients with six or more other conditions to 0.539 (CI=0.487-0.590) in the DMP group and to 0.398 (CI=0.338-0.457) for patients in RC. With the exception of patients with two other conditions, patients in the DMP have higher estimated mean values for all numbers of other conditions. A minimal important difference between DMP and RC existed for patients with four (DMP=0.627; RC=0.566), five (DMP=0.575; RC=0.510) and six or more (DMP=0.539; RC=0.398) other conditions (Table 1).

**CONCLUSIONS**

The results of our study demonstrate that participation in a DMP may have a greater impact on HRQoL for patients with type 2 diabetes and especially for those with increasing numbers of co-morbid conditions. We were able to show that the HRQoL decreased continuously and the difference between DMP and RC clearly increased as the number of other medical conditions rose. The study thus provides additional research evidence on the positive impact of German DMP, which is in line with previous studies (6,12). In addition, these results may suggest that the number of other medical conditions has an important influence on HRQoL.

The higher HRQoL in patients with type 2 diabetes with co-morbidity in the DMP group may be related to different factors. According to previous studies, structured chronic care may improve medical care for other conditions as well (13,14). This may be a result of both greater motivation on the part of the doctor to provide treatment and more opportunities to do so, as these patients visit the practice regularly. The finding may also reflect the added value of primary care, as this is by definition highly accessible, patient-oriented and comprehensive (15).

The study has some limitations. Firstly, because the DMP was established nationwide before our study began,
randomization was not possible. Furthermore, we do not know whether and how motivation to enroll in DMP affects the HRQoL, and differences (age, gender, DMP status) between responders and non-responders may also affect our results.

However, our findings suggest that having more other conditions may have a negative impact on the HRQoL of patients with type 2 diabetes. Our results demonstrate that primary care-based structured and coordinated care, such as that offered in the German DMP for type 2 diabetes, may help counterbalance this effect.

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**Table1**: Comparison of EQ5D score between type 2 diabetes patients in disease management and patients in routine care (n=1291)

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