

# Is There a Survival Benefit Within a German Primary Care–Based Disease Management Program?

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**M**anagement of diabetes and associated problems is one of the main challenges for healthcare systems worldwide. Patients with type 2 diabetes are likely to have multiple conditions (eg, coronary heart disease), and their life expectancy is shorter than that of individuals without diabetes.<sup>1,2</sup> In the United States, more than 60% of patients with diabetes die from cardiovascular causes.<sup>3</sup>

Interventions to improve the health status and life expectancy of patients with diabetes should focus on the patients and their individual problems as well as on a restructuring of care. Complex interventions that go beyond the adjustment of clinical parameters are required. The patient needs to be considered holistically in light of his or her individual circumstances. According to the literature, multifaceted interventions by multiprofessional teams with additional patient education and the enhancement of the role of practice nurses have been associated with improved diabetes care as well as patient outcomes.<sup>4</sup>

Diabetes disease management programs (DMPs) delivered in primary care settings were introduced into Germany nationwide in 2003.<sup>5</sup> Using compulsory requirements determined on behalf of the German Ministry of Health, sickness funds arrange contracts with primary care physicians. Participation for doctors and patients is voluntary, but participating doctors are obliged to keep within the conditions of the program. Primary care physicians and the wider practice teams, mostly in small- to medium-size practices in Germany, have a central role in performing and coordinating the provision of care to enrolled patients with diabetes.<sup>6</sup> The German DMPs have been designed to improve the quality of care for patients with chronic diseases, reduce complications, improve patient-oriented outcomes, and lower costs. Currently about 2.7 million patients with type 2 diabetes are enrolled.

The diabetes DMP includes the implementation and audit of evidence-based clinical guidelines using quality indicators and quality assurance measures, with feedback to participants on their level of performance. It also includes regular recalls for patients and shared individual goal setting by the patient and the physician, with consideration of the individual circumstances and risk profiles. This shared goal setting is based on emphasizing both coordination and continuity of care and

the physician's knowledge of each patient.<sup>7</sup> Patients are offered lifestyle advice with the aim of enabling them to achieve behavioral changes in diet and physical activity in support

**Objective:** To compare the mortality rate of patients with type 2 diabetes who were enrolled in the German diabetes disease management program (DMP) with the mortality rate of those who were not enrolled.

**Study Design:** This observational study was part of the ELSID study (Evaluation of a Large Scale Implementation of disease management programs) in Germany.

**Methods:** Participants had type 2 diabetes and were either enrolled or not enrolled in the DMP. The DMP provides systems-based, multifaceted, and patient-centered interventions. To reduce imbalances between the groups, a matched sample was created using sex, age, retirement status, federal state, pharmacy-based cost groups, and diagnostic-cost groups as matching criteria. Cox proportional hazards regression model and the Kaplan-Meier method were used to assess overall mortality. The observation period was 3 years beginning on January 1, 2006.

**Results:** A total of 11,079 patients were included in the analysis. As of January 1, 2006, 2300 patients were enrolled in the DMP and 8779 were receiving routine care. There were 1927 matched pairs of patients in the DMP group and the non-DMP group. The overall mortality rate was 11.3% in the DMP and 14.4% in the non-DMP group (log-rank test  $P < .01$ ).

**Conclusions:** We found an association between participation in the German diabetes DMP and reduced mortality. This reduced mortality cannot be attributed directly to the DMP. However, further research should evaluate whether a primary care–based DMP contributes to increased life expectancy in patients with diabetes.

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### Take-Away Points

Patients with type 2 diabetes who participate in the German primary care–based diabetes disease management program (DMP) receive systems-based, multifaceted, and patient-centered interventions.

- Participation in the DMP was associated with reduced mortality after 3 years.
- Although this reduced mortality cannot be attributed directly to the DMP, extension of the approach within primary care may contribute to increased life expectancy for patients with diabetes.

of their own self-management. The doctor-patient relationship is strengthened within the program, and continuity of care is guaranteed as patients are obliged to visit their physician regularly, either quarterly or semiannually. There also is an enhanced role for doctors' assistants within the DMP. Patients enrolled in the program are more likely to receive diabetes care according to the chronic care model<sup>6</sup> than patients who are not enrolled.

Statutory nationwide evaluation of all DMPs is mandatory for all sickness funds. However, patients enrolled in a DMP are not compared with patients who are not. Although reducing mortality is a patient-relevant outcome of interventions and new models in diabetes care, it often is not measured in trials.<sup>8</sup> The reason may be that it is difficult and expensive to design studies in this area to evaluate the impact of specific interventions on mortality.

The aim of this observational study was to report the mortality rates of patients with type 2 diabetes enrolled in the German diabetes DMP compared with the mortality rates of patients who are not enrolled in the program, but who receive routine care.

## METHODS

### Setting

This analysis was carried out as part of the ELSID study (Evaluation of a Large Scale Implementation of disease management programs), which is a 2-armed controlled trial to evaluate the effectiveness of the German diabetes DMP. The first arm is described elsewhere.<sup>9</sup> The second arm, on which the present analysis was based, was observational. The study team made no additional intervention and did not influence participation in the DMP. The ELSID study was conducted in 2 federal states of Germany (Rheinland-Pfalz and Sachsen-Anhalt) and was fully approved by the ethics committee of the Medical Faculty of the University of Heidelberg.

### Participants

All of the participants in this study were insured by 1 large statutory regional healthcare fund called the Allgemeine Ortskrankenkasse (AOK), which covers about 40% of the German

population. The prevalence data were provided by the AOK. For Sachsen-Anhalt, data also were provided by the regional Association of Statutory Health Insurance Physicians. Patients were identified from routine claims data from the AOK. To be included in the study, patients had to be older than age 50 years and be receiving a prescription for antidiabetic medica-

tion (oral antidiabetic drugs or insulin) in the first half-year of 2005. Patients who were managing their diabetes by diet alone were excluded from analysis. Patients in the DMP group had to be enrolled in the program by December 31, 2005, regardless of how long they had participated in the program prior to that date. Patients in the non-DMP group were not enrolled in the DMP before this appointed date. In the non-DMP group, all of the patients who joined the DMP during the observational time were excluded from analysis. Therefore, the number of patients in the non-DMP group was deliberately larger from the beginning, because we did not know how many patients would subscribe to the DMP during the study.

Participation in the DMP is voluntary for both patients and primary care physicians; physicians get financial remuneration for participating patients. Patients are informed of the existence of these programs by their primary care physician and their sickness fund. Patients could subscribe only to the program attended by their primary care physician. Using the claims data, all of the patients were assigned to their primary care physician as a cluster.

### Matching

In order to reduce imbalances between DMP and non-DMP patients at baseline in terms of sex, age, and other variables, we matched the sample according to the study protocol.<sup>9</sup> To create matched pairs with regard to the illness burden, we used a matching method based on pharmacy-based cost groups (PCGs) as an outpatient morbidity measure and marker for chronic conditions based on the prior prescription of medication<sup>10</sup> and diagnostic cost groups (DCGs) with inpatient diagnostic information from prior hospitalizations.<sup>11,12</sup> This method was developed in the Netherlands for application within the national risk structure compensation scheme.

The matching criteria in the ELSID study were age group (from age 50 years in consecutive steps of 5 years to >90 years), sex, retirement status (yes or no), federal state (Sachsen-Anhalt, Rheinland-Pfalz), PCG, and DCG. For each patient in the DMP group, an appropriate matching partner from the non-DMP group was identified if possible. It was necessary for the age group, sex, retirement status, and federal

**Table 1.** Sociodemographic Data

Characteristic	Before Matching			After Matching		
	DMP (n = 2300)	Non-DMP (n = 8779)	P	DMP (n = 1927)	Non-DMP (n = 1927)	P
<b>Female, No. (%)</b>	1364 (59.3)	5361 (61.1)	.124	1162 (60.3)	1162 (60.3)	—
<b>Mean age, y (SD)</b>	70.47 (8.88)	72.80 (9.63)	<.001	70.70 (8.6)	70.73 (8.57)	.933
<b>Federal state Sachsen-Anhalt, No. (%)</b>	1366 (59.4)	6047 (68.9)	<.001	1204 (62.5)	1204 (62.5)	—
<b>No. of PCGs</b>						—
Mean (SD)	1.88 (1.24)	1.71 (1.18)	<.001	1.75 (1.31)	1.75 (1.31)	
Median (IQR, 25%-75%)	2.00 (1.00-3.00)	2.00 (1.00-2.00)		2.00 (1.00-2.00)	2.00 (1.00-2.00)	
<b>No. of DCGs</b>						—
Mean (SD)	0.28 (1.2)	0.40 (1.3)	<.001	0.05 (0.44)	0.05 (0.44)	
Median (IQR)	0.00 (0.00-0.00)	0.00 (0.00-0.00)		0.00 (0.00-0.00)	0.00 (0.00-0.00)	
<b>Prescription of insulin, No. (%)</b>	971 (42.2)	3318 (37.8)	<.001	794 (41.2)	751 (39.0)	.158

DCG indicates diagnostic cost group; DMP, disease management program; IQR, intraquartile range; PCG, pharmacy-based cost group.

state, as well as the most expensive PCG and DCG and the total number of PCGs and DCGs, to be consistent between the matching partners.

We used the MatchBalance() function of R’s package “Matching” to test whether matching was balanced on baseline covariates.<sup>13</sup>

**Outcomes**

The primary outcome of this analysis was the overall mortality (death from all causes) for matched pairs of DMP and non-DMP patients. The observation period was 3 years, beginning on January 1, 2006. Survival times were censored for patients who were still alive on December 31, 2008.

As a secondary outcome measure, the unadjusted overall mortality of the unmatched sample also was analyzed.

**Statistical Analysis**

The data were analyzed using SPSS version 15.0 (SPSS Inc, Chicago, IL). Baseline characteristics were analyzed using the Student *t* test or the Mann-Whitney test for continuous variables and the  $\chi^2$  test for categorical variables as appropriate (after testing for normal distribution with the Kolmogorov-Smirnov test). Survival curves were constructed using the Kaplan-Meier method; the group differences between DMP and non-DMP patients were analyzed by the log-rank test. Hazard ratios and 95% confidence intervals (CIs) were calculated with the Cox proportional hazards regression model.

Within the primary analysis of the matched pairs, we only included group membership (DMP vs non-DMP) in the univariate model, as the other variables had been used previously

as matching criteria. Within the secondary analysis of the whole sample in the final multivariate regression model, we included age, sex, federal state, and group membership (DMP vs non-DMP). A potential cluster effect also was considered by including binary variables for the clusters (ie, primary care physicians) in the model. The level of significance was *P* <.05.

**RESULTS**

A total of 11,079 patients were included in our analyses. Of these, 2300 were enrolled in a DMP and 8779 received routine care. **Table 1** shows the sociodemographic characteristics of these patients.

Compared with patients receiving routine care, patients in the DMP were younger, with a mean  $\pm$  SD age of 70.47  $\pm$  8.88 years versus 72.80  $\pm$  9.63 years for non-DMP patients (*P* <.001). The patients within the DMP group had a higher total number of PCGs (*P* <.001) and a lower number of DCGs (*P* <.001), as can be seen in Table 1.

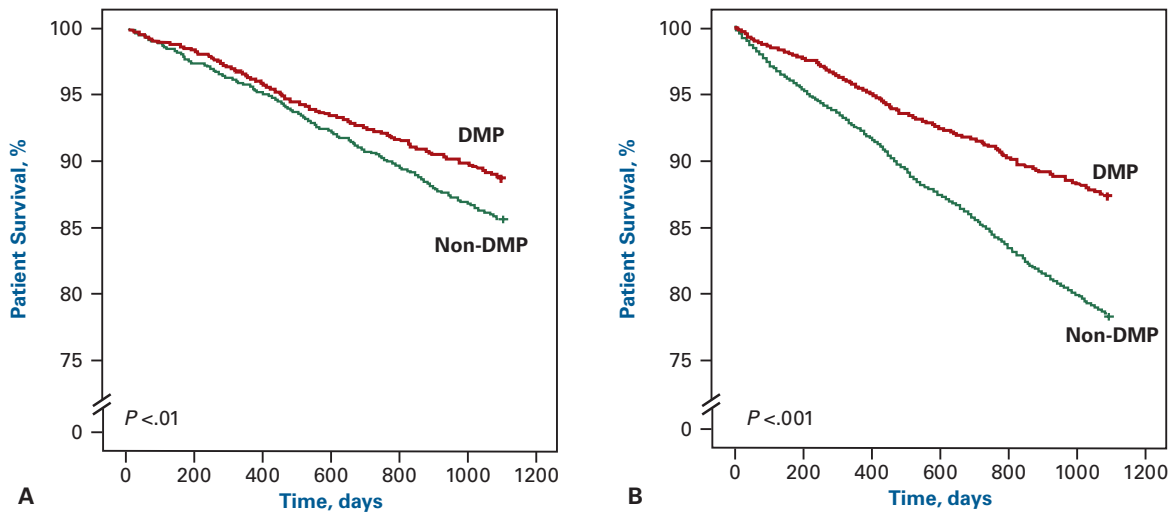
**Matched Pairs**

Matched pairs of patients (n = 1927 pairs) were identified and analyzed. The sociodemographic characteristics of these subgroups are shown in Table 1. We were able to confirm that matching was balanced on all baseline covariates with the MatchBalance() function of R’s package Matching.

**Mortality Data**

The overall mortality (death from all causes) within the 2 groups of matched pairs was 11.3% within the DMP group

■ **Figure.** Kaplan-Meier Survival Curves for the Matched Pairs (A) and the Total Sample (B)



DMP indicates disease management program.

and 14.4% within the non-DMP group (log-rank test  $P < .01$ ). Mortality, therefore, was significantly lower in the DMP group. Panel A of the **Figure** shows the patient survival data for the matched pairs (Kaplan-Meier curve). In the univariate analysis of the matched sample, nonparticipation was associated with an increased hazard ratio of 1.3 (95% CI = 1.09, 1.55;  $P < .01$ ).

The overall mortality in the total sample was 12.8% for the group of patients enrolled in the DMP and 21.7% for the patients receiving routine care ( $P < .001$ ). Panel B of the **Figure** shows the unadjusted patient survival rate (Kaplan-Meier curve) for these 2 groups. Considering all of the variables within the final Cox regression model, nonparticipation in the DMP, higher age, and federal state were significant predictors of mortality. The adjusted hazard ratio for nonparticipation was 1.46 (95% CI = 1.28, 1.65;  $P < .001$ ).

These data show that the mortality risk was significantly lower for patients participating in the DMP. **Table 2** shows the univariate and multivariate hazard ratios of the Cox proportional regression model.

## CONCLUSION

This evaluation, which focused on the German diabetes DMP, shows an association between participation in the DMP and a reduction in all-cause mortality, even when patients were matched on sociodemographic variables and cost groups. It was possible to observe similar results when the whole sample was analyzed.

Several evaluation studies demonstrate a benefit for patients who participated in a DMP. For example, participation

is associated with a reduced rate of hospitalization in general and for patients with type 2 diabetes in particular.<sup>14,15</sup>

Because of the observational design of this study, the data cannot be used to attribute a direct and causal link between enrollment in the diabetes DMP and differences in mortality. However, some factors may contribute to the association between DMP participation and reduced mortality. First, it may be hypothesized that disease management contributes to improved care for patients with diabetes. The German diabetes DMP requires registered physicians to focus on controlling risk factors for diabetes complications and for the risk of a cardiovascular event, taking into consideration the comorbidities of the patients. The DMP also promotes an emphasis on the continuity and coordination of care.<sup>7</sup> This emphasis leads to a restructuring of chronic illness care according to models such as the chronic care model<sup>16</sup> and the medical home concept.<sup>17</sup> Both models stress that the responsibility for individual care and coordination rests with medical providers working together within a healthcare team.

Daaleman describes a primary care practice within a medical home as a place in which standards of excellence and adherence to guidelines coexist with the achievement of goals and special support for patients with diseases, disability, or dysfunction.<sup>17</sup> He also mentions health education and prevention, as well as development and promotion of quality improvement measures and evidence-based treatment, as important elements of care in the medical home movement. Moreover, a positive association between continuity of care and glycemic control has been reported.<sup>18</sup> Within a community-based DMP intervention in China, improved continuity of care was associated with improved patient health outcomes.<sup>19</sup>

■ **Table 2. Hazard Ratios**

Parameter	Univariate Hazard Ratio (95% CI) <sup>a</sup>	P	Multivariate Hazard Ratio (95% CI) <sup>b</sup>	P
Group (DMP vs non-DMP)	1.300 (1.089, 1.553)	<.01	1.456 (1.282, 1.654)	<.001
Sex	—	—	0.680 (0.621, 0.746)	<.001
Age	—	—	1.089 (1.083, 1.094)	<.001
Federal state	—	—	1.151 (1.048, 1.263)	<.01

CI indicates confidence interval; DMP, disease management program.  
<sup>a</sup>Analysis of the matched pairs.  
<sup>b</sup>Analysis of the total sample.

Rothman and Wagner suggest that disease management may contribute to improved care, especially when continuity and coordination of care are reinforced in the primary care setting.<sup>7</sup> It also is possible that the reduced mortality in diabetes DMPs is related to the enrolled patients receiving more social support from their physician and doctor’s assistant, who is more involved in patient care. Previous research has shown that social support and social participation are associated with lower mortality.<sup>20,21</sup> However, there are different definitions of social support. Dalgard and Lund Håheim describe social support as relationships with other people during stressful life situations,<sup>22</sup> whereas others describe social support as being emotional, informational, and material support.<sup>23</sup> All of these elements are core aspects of the German DMP. A body of research suggests that primary care–orientated healthcare systems are associated with better health outcomes and reduced all-cause mortality, even in populations with health and income inequalities in the United States. Industrialized nations in which primary care is promoted over specialist care generally achieve better health outcomes at lower overall costs.<sup>24</sup>

Several limitations of this study have to be discussed. Because we only analyzed claims data, there was no structured documentation of the causes of death, and we could only evaluate all-cause mortality. However, it is known from other studies that most individuals with diabetes die from cardiovascular disease.<sup>5,25</sup> Another limitation that might limit the generalizability of the findings is that participants in our study were all from the same regional health fund, which has a higher proportion of elderly insureds and a higher prevalence of multimorbidity than other insurers in Germany. In addition, we were unable to assign doctors and patients to the study groups at random because (1) participation in the DMP in Germany is voluntary and (2) our study was conducted after the nationwide implementation of the DMP within a short time frame.

Before matching, our 2 groups had limited comparability. Unfortunately we were not able to consider levels of education when we matched the patients because the appropriate data were not available. However, we know from another

analysis of DMP participants and nonparticipants in Germany that people who are less ill are not overrepresented in the DMP and that there is only a nominal social strata gradient between participants and nonparticipants.<sup>26</sup> Furthermore, information from another part of the ELSID study indicates that there were no significant differences between DMP participants and nonparticipants with respect to level of education and annual income.<sup>6</sup>

We cannot be completely sure that there is no selection bias within the sample; participating patients could be more health conscious and compliant. That may be another reason for an association between participation and reduced mortality. Furthermore, other confounders could influence mortality (eg, diabetes duration). We were not able to analyze diabetes duration for the whole sample, but self-reported information about diabetes duration did exist for about 300 patients in each group. Diabetes duration was 13.43 years within the routine-care group and 12.08 years within the DMP group, which was not a significant difference ( $P = .107$ ). We do not know why either doctors or patients chose not to participate in the DMP. As there is an ongoing political discussion about the role of DMPs in Germany, it is possible that some nonparticipating doctors were opposed to the programs and therefore did not take part. There also could be some selection bias concerning motivation for participation and awareness of problems in diabetes care. Further evaluation of the German DMP must address the issues of self-selection and selection bias.

Moreover, we assessed the effect of the diabetes DMP as a whole and could not differentiate between single elements of the DMP with regard to their contribution to reduced mortality. It is probable that these elements work effectively together. A recent systematic review found that the most effective interventions to improve diabetes care were complex and included 4 areas of care: changing of clinician behavior, changes in how practices are organized, information systems enhancement, and educational support for the patient.

The strengths of our study are the large and heterogeneous sample, and selection criteria that used routine claims data. Moreover, we conducted an analysis of matched data and

found significant differences for patients enrolled in the diabetes DMP after controlling for sociodemographic data and disease severity.

The German diabetes DMP is a systems-based, multifaceted, patient-centered, and primary care-based intervention. As delivered in Germany, DMPs integrate the perspectives of health-care providers and patients within primary care settings. They seek to address the growing demands of an aging population with a greater prevalence of chronic illness and multimorbidity. Our preliminary analyses found that matched patients with type 2 diabetes enrolled in the diabetes DMP had a significantly reduced mortality rate compared with patients not enrolled in the program. We cannot prove a direct and causal link between this outcome and the DMP. Further research is required to evaluate whether the DMP program approach within primary care settings contributes to increased life expectancy in patients with type 2 diabetes and other chronic conditions.

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