

Disease Management Programs in Type 2 Diabetes: Quality of Care

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Diabetes mellitus is an important risk factor for macrovascular and microvascular disease.¹ According to the Diabetes Atlas of the International Diabetes Federation, Germany is one of the countries with the highest prevalence of type 2 diabetes worldwide. Quality of care of chronic diseases may be expected to improve within disease management programs (DMPs) because DMPs implement evidence-based clinical practice guidelines, and educational and quality control measures.²⁻⁶ Since 2002 some of the world's largest DMPs have been launched in Germany; the ones for type 2 diabetes were among the first (enrollment began in June 2003) and are the largest DMPs in Germany.⁷ About 88% of the German population is insured with the compulsory statutory health insurance system. About 1 out of 13 of these patients, totaling about 5.5 million, is enrolled in a DMP. It has been estimated that in 2006 about 75% of all general practitioners and approximately 65% of all patients with type 2 diabetes were participating in diabetes DMPs.⁸

Previous studies have shown that, after implementation of guidelines and organizational improvement efforts, process outcomes but not necessarily patient outcomes are improved.^{3,9} The effects on patient outcomes may often be less clear because they have rarely been assessed.³ The official journal of the German Medical Association stated, based on data either unpublished or provided from health insurance companies, that patients who participate in DMPs receive better care than the ones that do not.¹⁰ Although DMPs for type 2 diabetes have been substantially subsidized, studies investigating their effectiveness, which are even required by law (Social Code Book V, paragraph 137f), are by and large missing. Inherent methodologic problems of such studies have been discussed intensely, but the stakeholders have been reluctant to support the suggested necessary randomized trials.¹¹ Interestingly, randomized trials examining the effectiveness of diabetes DMPs have been performed in various countries implementing them, such as (among others) China, Thailand, South Korea, Canada, and the United Kingdom (reviewed by Pimouguet et al¹²), although these trials are limited by small numbers and examined A1C measurements only.

It is likely that improvements in quality of care are confounded by secular trends, rendering historical control groups unsuitable. Prospective

nonrandomized studies are problematic due to the relatively high probability of selection bias causing confounding. Randomized trials, generally

Objectives: To determine whether disease management programs (DMPs) for type 2 diabetes mellitus (T2DM) can improve some processes of care and intermediate outcomes.

Study Design: Two cross-sectional registries of patients with T2DM were used for data extraction before (previous cohort) and after (recent cohort) introduction of DMPs in Germany (N = 78,110).

Methods: In the recent cohort, 15,293 patients were treated within the DMPs and 9791 were not. Processes of care, medications, and intermediate outcomes (achievement of treatment targets for low-density lipoprotein [LDL] cholesterol, blood pressure, and glycosylated hemoglobin [A1C]) were analyzed using multivariable, multilevel logistic regression, adjusting for patient case-mix and physician-level clustering to derive odds ratios and 95% confidence intervals (CIs).

Results: Availability of structured diabetes education and of lipid, blood pressure, and A1C measurements increased over time. In DMP patients, availability was significantly higher for blood pressure and A1C but not for lipid measurements. Prescription of angiotensin-converting enzyme inhibitors, oral antidiabetic drugs, and insulin increased over time and was more common in DMP patients. Statin prescription increased over time but was not influenced by DMP status. Intermediate outcomes improved over time, but DMPs had no influence on intermediate outcomes except for reaching LDL cholesterol targets (odds ratio 1.12 [95% CI 1.06, 1.19] in favor of DMPs).

Conclusions: While there may be some unmeasured confounding, our data suggest that improvement in processes of care by DMPs, as implemented in Germany, only partially translates into improvement of intermediate outcomes.

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Take-Away Points

A 2-level cross-sectional study investigating registries of patients with type 2 diabetes mellitus in 2003 and 2007 found that disease management programs (DMPs) were not effectively influencing intermediate outcomes.

- Processes of care improved over time.
- Intermediate outcomes (target achievement for lipids, blood pressure, and glycosylated hemoglobin) improved over time.
- However, there were no relevant differences in target achievements between patients who participated in DMPs and patients who did not participate in DMPs.

believed to be the gold standard for prospective controlled studies, are difficult to perform, at least under the conditions of German diabetes DMPs, since criteria for the inclusion of patients enforce preselection. For example, an integral part of the DMPs is the willingness and motivation of the patient to actively pursue treatment goals—the participating physician confirms that he or she includes only patients fulfilling these criteria. It can therefore be expected that basic treatment measures such as weight loss, physical exercise, dietary changes, and smoking cessation are more frequent in patients participating in DMPs compared with patients who are not, therefore improving outcomes. On the other hand, it could be that patients with higher risk or more comorbidities are encouraged to participate in DMPs, therefore resulting in underestimation of DMPs' potentially positive effect.

There is evidence suggesting that quality of diabetes care improves over time (secular trends).¹³ The purpose of the present study was to examine (1) whether secular trends show improved processes of care and intermediate outcomes between the years 2002 and 2003 and 2006 and 2007 and (2) whether patients within DMPs receive better processes of care and achieve intermediate outcomes more often compared with non-DMP patients. Data from 2 large cross-sectional diabetes registries, the DUTY¹⁴ and the LUTZ¹⁵ registries, were used. Primary intermediate outcome parameters were proportions of subjects reaching target values for lipid levels, blood pressure, and glycemia.

METHODS

Study Design and Participants

The study is a 2-level cross-sectional trial in outpatients with type 2 diabetes performed in the years 2002-2003 ("previous cohort," before the introduction of DMPs, N = 53,026) and 2006-2007 ("recent cohort," after the introduction of DMPs, N = 25,084) in Germany. In the previous cohort we used the data from the DUTY registry (Diabetes mellitus needs unrestricted evaluation of patient data to yield treatment progress), while in the recent cohort we used data from the LUTZ registry (Lipidmanagement und Therapieziel-

Erreichung; lipid management and achievement of treatment targets). Study protocols were approved by the Ethics Committee of the Bavarian Chamber of Physicians. The study designs have been published before.¹⁴⁻¹⁹

In short, in the DUTY registry 6700 office-based physicians (general practitioners, internists, and diabetologists) were approached to participate in the

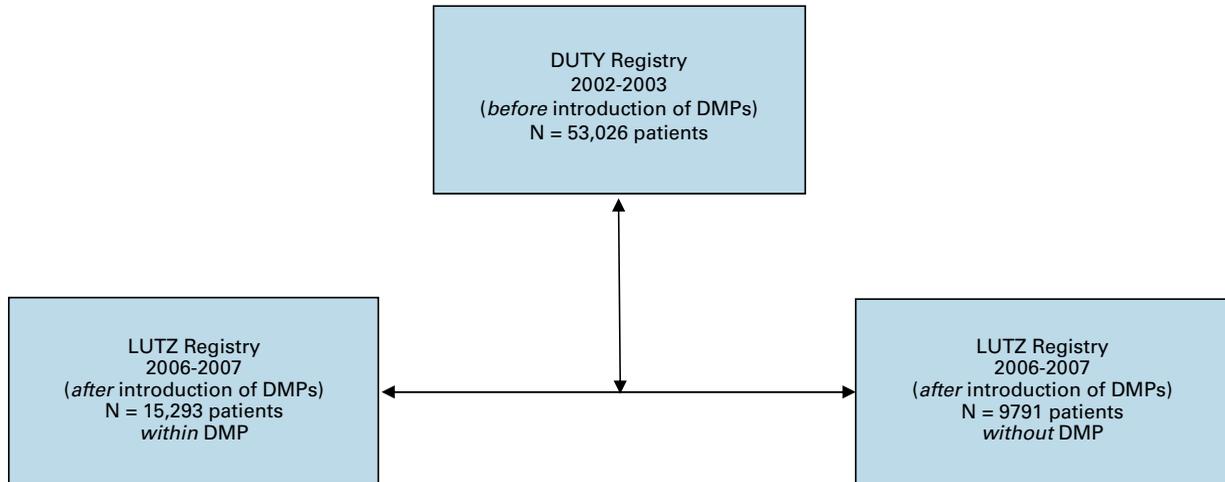
study. Each physician was asked to recruit 20 consecutive patients with type 1 or type 2 diabetes under his or her treatment. The diagnosis of diabetes was established by the reporting physician. Reports on 59,075 patients were received. Of these patients, 89.8% had type 2 diabetes, 5.7% type 1 diabetes, and in 4.5% the type of diabetes was not identified. For the present evaluation, only patients with type 2 diabetes were considered. Thus, data of 53,026 patients were analyzed, obtained from 3096 physicians.

In the LUTZ registry, 6551 office-based physicians (general practitioners, internists, cardiologists, and diabetologists) were invited to participate, irrespective of whether they took part in DMPs or not. They were requested to include 6 consecutive patients with diabetes and/or coronary heart disease (CHD). In practices that participated in a DMP, this sample was to be balanced (3 patients in any DMP, 3 non-DMP patients). The large majority of physicians (93.1%) took part in a DMP. Of those, 61.1% participated in DMPs for CHD and diabetes, 10.3% for diabetes alone, and 2.5% for CHD alone; in 25.7% of the cases the type of DMP was unspecified. Practices that did not participate in a DMP accounted for 6.7% (0.4% not reported). A total of 45,873 patients were documented in the registry. Only the ones with the diagnosis of type 2 diabetes were included (N = 25,084). Of these patients, 15,293 were treated within diabetes DMPs and 9791 were not (Figure 1). Among the patients in the diabetes DMPs, 21.5% were also in a DMP for CHD, and 8.9% of the ones not in a diabetes DMP were in a DMP for CHD.

Description of Disease Management Programs

The German type 2 diabetes DMPs are multifaceted and patient-centered interventions that are implemented within the nationwide statutory health insurance system by primary care physicians. Participation is voluntary for both patients and physicians. Medical services in the DMPs include a defined frequency of physician visits, rules for referral to a diabetologist, regular foot and eye examinations, physician counseling regarding lifestyle changes (eg, nutrition, smoking, and exercise), participation in diabetes education

■ **Figure 1.** Study Participant Flowchart



courses, and agreement on target values for A1C and blood pressure between the physician and the patient. Further elements of the DMPs are documentation of the course of disease and treatment every 3 to 6 months as well as automated reminders for physicians and patients.²⁰ For more information on the DMP contents, a typical contract between health insurers and associations of statutory health insurance physicians can be accessed online: http://www.kvno.de/downloads/dmp_diab2_vertrag.pdf.

Definition of Variables

We defined general clinical management measures as processes of care (determinations of LDL cholesterol, blood pressure, A1C values, documentation of smoking status, providing structured diabetes education), medications (prescription of statins, angiotensin-converting enzyme [ACE] inhibitors, oral antidiabetic agents, insulin, and thrombocyte aggregation inhibitors), and intermediate outcomes, which were defined as achieving the recommended target values as specified by American Diabetes Association guidelines,²¹ namely, proportions of patients achieving LDL cholesterol concentrations of <100 mg/dL; systolic and diastolic blood pressure of <130 and <80 mm Hg, respectively; and A1C of <7%. Nonavailability of the data was considered to indicate that targets were not achieved.

Coronary heart disease was defined as a history of angina (stable or unstable), myocardial infarction, percutaneous transluminal coronary angioplasty, or coronary artery bypass graft surgery. Cerebrovascular disease was defined as history of stroke or transient ischemic attack. Individuals were considered to have peripheral arterial disease if they had a history of intermittent claudication, defined as posterior calf pain on walking relieved by rest and/or prior limb arterial re-

vascularization. Diagnoses of CHD, cerebrovascular disease, and peripheral arterial disease were made based on the physicians' clinical judgment. The presence of atherosclerotic disease was assumed when 1 or more diagnoses such as CHD, cerebrovascular disease, or peripheral arterial disease were present.

Statistical Analysis

We conducted univariate analyses to describe patient characteristics and reported means and SDs for continuous variables, and frequencies and percentages for categorical variables. We calculated *P* values for differences between the previous and the recent cohort and between DMP and non-DMP patients (within the recent cohort), using *t* tests or Fisher's exact test where appropriate.

In a multivariable, multilevel model we investigated the influence of time (secular trends) on processes of care and intermediate outcomes and the influence of DMPs. We adjusted for patient case-mix variables using sex (as a categorical variable), age (as a continuous variable), body mass index (as a continuous variable), and concomitant atherosclerotic disease (as a categorical variable). For each process and outcome measure, these logistic regression models were used to calculate estimated odds ratios (ORs) and 95% confidence intervals (CIs) comparing in a first step the influence of time (recent vs previous cohort) and in a second step the influence of DMPs. In this second model, additional adjustments were made for time (as an ordinal variable). In all multivariable models we used generalized estimating equations to investigate the additional effects (beyond case-mix bias) of physician-level clustering on significance testing. The model thus contained 2 levels, the physician's practice and the patient. It was constructed this way to account for

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■ **Table 1.** Patient Demographic Characteristics, Concomitant Diseases, General Clinical Management Measures, Medications, and Target Achievement (N = 78,110)^a

| Variable | 2002-2003 (n = 53,026) | 2006-2007 (n = 25,084) | P ^b | 2006-2007 DMP (n = 15,293) | 2006-2007 Non-DMP (n = 9791) | P ^c |
|---|---------------------------|---------------------------|----------------|----------------------------------|------------------------------------|------------------|
| Demographic characteristics | | | | | | |
| Male, % | 48.6 | 56.8 | <.0001 | 56.0 | 58.0 | .002 |
| Age, y | 65.2 ± 10.9 | 65.9 ± 10.5 | <.0001 | 66.1 ± 10.1 | 65.7 ± 10.9 | <.0001 |
| Body mass index, kg/m ² | 28.9 ± 4.7 | 29.8 ± 5.1 | <.0001 | 30.0 ± 5.1 | 29.5 ± 5.0 | <.0001 |
| Concomitant diseases and complications, % yes | | | | | | |
| Atherosclerotic disease | 39.3 | 41.7 | <.0001 | 42.1 | 41.1 | .14 |
| Coronary heart disease | 27.8 | 32.7 | <.0001 | 33.2 | 31.9 | .04 |
| Cerebrovascular disease | 7.5 | 7.7 | .34 | 7.6 | 7.9 | .41 |
| Peripheral arterial disease | 10.4 | 10.4 | .85 | 10.8 | 9.9 | .03 |
| General clinical management measures, % yes | | | | | | |
| Smoking | 17.1 | 19.2 | <.0001 | 19.2 | 20.7 | <.0001 |
| Structured diabetes education | 40.1 | 63.0 | <.0001 | 76.0 | 42.8 | <.0001 |
| LDL cholesterol determination available | 85.0 | 96.4 | <.0001 | 96.6 | 96.3 | .42 |
| Blood pressure measurement available | 97.5 | 98.8 | <.0001 | 99.0 | 98.4 | <.0001 |
| A1C determination available | 99.2 | 96.0 | <.0001 | 97.3 | 94.0 | <.0001 |
| Drug therapy, % yes | | | | | | |
| Statin | 25.5 | 51.1 | <.0001 | 51.3 | 50.8 | .41 ^d |
| ACE inhibitor | 42.4 | 64.5 | <.0001 | 66.2 | 61.8 | <.0001 |
| Oral antidiabetic agent(s) | 66.0 | 63.8 | <.0001 | 65.5 | 61.1 | <.0001 |
| Insulin | 23.5 | 30.0 | <.0001 | 33.6 | 24.5 | <.0001 |
| Thrombocyte aggregation inhibitor(s) | ND | ND | | 37.9 | 37.9 | .99 |
| Lipoprotein, blood pressure, and A1C values | | | | | | |
| Total cholesterol, mg/dL | 225 ± 51 | 216 ± 54 | <.0001 | 214 ± 53 | 218 ± 54 | <.0001 |
| LDL cholesterol, mg/dL | 136 ± 39 | 128 ± 89 | <.0001 | 127 ± 95 | 130 ± 79 | <.0001 |
| HDL cholesterol, mg/dL | 49 ± 14 | 52 ± 39 | <.0001 | 52 ± 39 | 52 ± 38 | .74 |
| Triglycerides, mg/dL | 215 ± 264 | 230 ± 425 | <.0001 | 232 ± 512 | 227 ± 229 | .37 |
| Systolic blood pressure, mm Hg | 143 ± 18 | 138 ± 15 | <.0001 | 137.5 ± 15 | 138.1 ± 15 | .003 |
| Diastolic blood pressure, mm Hg | 83 ± 10 | 81 ± 9 | <.0001 | 81 ± 9 | 82 ± 9 | <.0001 |
| A1C, % | 7.29 ± 1.29 | 7.09 ± 1.22 | <.0001 | 7.11 ± 1.11 | 7.08 ± 1.38 | .09 |
| Intermediate outcomes (treatment targets achieved), % yes | | | | | | |
| LDL cholesterol <100 mg/dL | 13.9 | 26.8 | <.0001 | 27.7 | 25.4 | .0001 |
| Systolic blood pressure <130 mm Hg | 15.9 | 21.5 | <.0001 | 21.7 | 21.0 | .17 |
| Diastolic blood pressure <80 mm Hg | 19.9 | 25.4 | <.0001 | 25.8 | 24.7 | .04 |
| A1C <7% | 44.4 | 51.3 | <.0001 | 50.8 | 52.0 | .051 |

A1C indicates glycosylated hemoglobin; ACE, angiotensin-converting enzyme; DMP, disease management program; HDL, high-density lipoprotein; LDL, low-density lipoprotein; ND, no data.

^aContinuous variables are presented as means ± SD. Categorical variables are presented as proportions (percentage). Comparisons were performed using unpaired *t* tests in the case of continuous variables and Fisher's exact test in the case of categorical variables.

^bUnadjusted *P* values for comparisons of the previous cohort (2002-2003) with the recent cohort (2006-2007).

^cUnadjusted *P* values for comparisons of DMP with non-DMP patients *within* the recent cohort (2006-2007).

^dThe lack of a significant difference was not influenced by parallel enrollment (or not) in a DMP for coronary heart disease. Proportions of patients in coronary heart disease DMPs who received a statin were 52.6% and 53.5% (diabetes DMP no or yes, respectively), and proportions of patients not in coronary heart disease DMPs who received a statin were 50.6% and 50.7% (diabetes DMP no or yes, respectively).

the correlation between patients within practices and to take advantage of the information contained in these correlations. Formal inferences of significance were based on the Wald test.

We used the statistical software Stata version 9 (StataCorp, College Station, Texas). We used Stata's *xtgee* command to model panel data. All reported *P* values are 2-sided and considered significant at $<.05$.

RESULTS

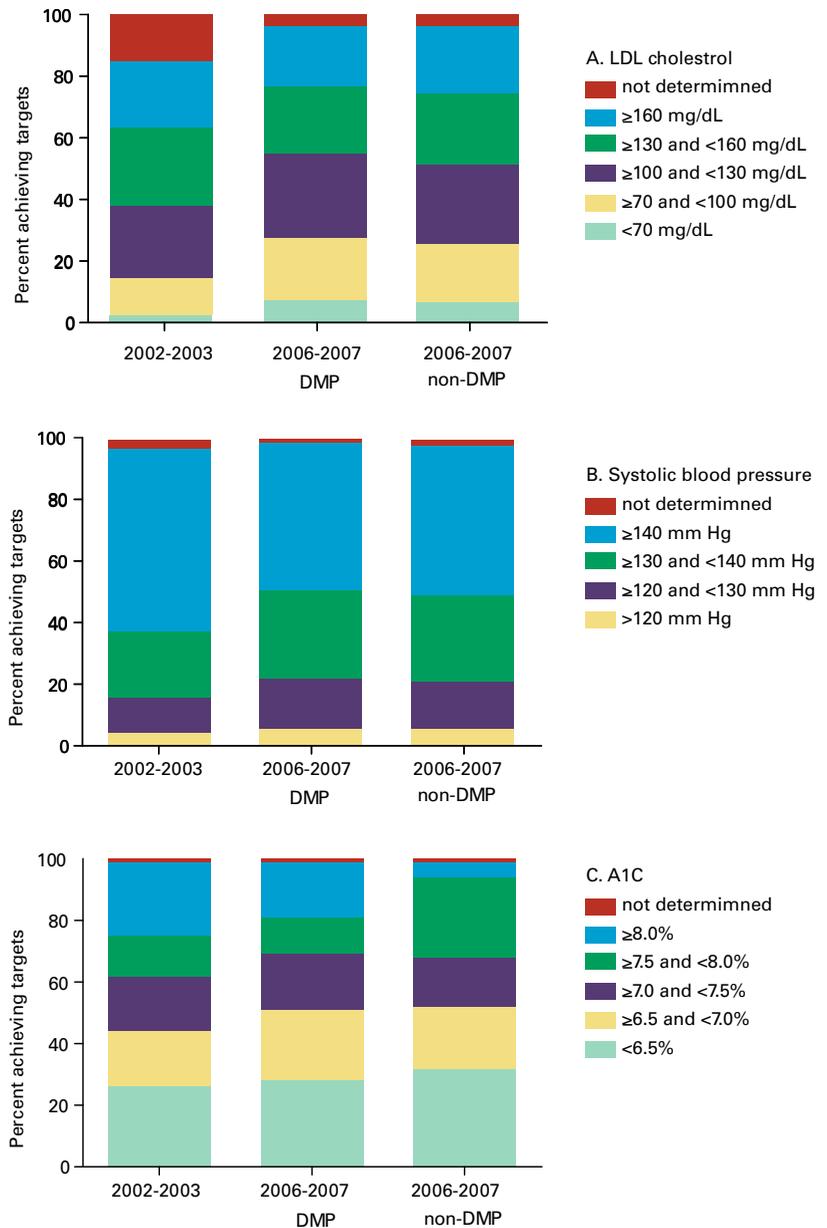
Univariate Analyses

Results of univariate analyses are shown in **Table 1**. There were significantly more male patients in the recent cohort than in the previous cohort and slightly fewer male patients in DMPs than in non-DMPs. Patients in the recent cohort were slightly but significantly older, and those in the DMPs were significantly older. Body mass index (BMI) increased over time and patients in DMPs had a higher BMI than non-DMP patients.

The overall proportion of secondary prevention patients (as indicated by the presence of atherosclerotic disease) increased slightly but significantly over time (from 39.3% to 41.7%), mostly due to an increase in CHD, but there was no difference in the proportions between DMPs and non-DMPs.

The overall proportion of smokers increased over time. The increase was entirely due to an increase in smoking in females (data not shown). There were fewer smokers in DMPs compared with non-DMPs. The proportion of patients receiving structured diabetes education increased from 40.1% to 63% over time and was much higher in DMP patients compared with non-DMP patients (76% vs 42.8%). The availability of LDL cholesterol measurements increased substantially over time (from 85% to 96.4%), but was not different between DMP patients and non-DMP patients. The availability of blood pressure measurements was $>97.5\%$ in all groups, with slight but significant increases over time, and was higher in DMP compared with non-DMP patients. The availability of A1C

Figure 2. Percentage of All Patients Reaching Treatment Targets for (A) LDL Cholesterol, (B) Systolic Blood Pressure, and (C) A1C



A1C indicates glycosylated hemoglobin; DMP, disease management program; LDL, low-density lipoprotein.

measurements decreased over time, but was higher in DMP patients compared with non-DMP patients.

Statin therapy increased substantially over time (from 25.5% to 51.1%), but was not different between DMP and non-DMP patients. The lack of difference was not influenced by the simultaneous enrolment in a DMP for CHD (for details see **Table 1**). Prescription of ACE inhibitors increased substantially over time (from 42.4% to 64.5%) and was sig-

■ **Table 2.** Multivariable Analysis: Influence of Secular Trends and Type 2 Diabetes Disease Management Programs on Processes of Care and Intermediate Outcomes

| Variable | Influence of Secular Trends ^a | | | Influence of DMPs ^b | | |
|---|--|------------|--------|--------------------------------|------------|--------|
| | OR ^c | 95% CI | P | OR ^d | 95% CI | P |
| BMI ^e <30 kg/m ² | .66 | .65, .69 | <.0001 | .84 | .80, .89 | <.0001 |
| General clinical management measures | | | | | | |
| Being a nonsmoker | .84 | .80, .87 | <.0001 | 1.13 | 1.05, 1.21 | <.0001 |
| Receiving structured diabetes education | 2.54 | 2.46, 2.63 | <.0001 | 4.26 | 4.03, 4.51 | <.0001 |
| Having LDL cholesterol determined | 4.60 | 4.26, 4.96 | <.0001 | 1.03 | .90, 1.19 | .65 |
| Having blood pressure measured | 2.74 | 2.37, 3.17 | <.0001 | 1.52 | 1.17, 1.98 | .002 |
| Having A1C determined | .16 | .14, .19 | <.0001 | 2.26 | 1.98, 2.59 | <.0001 |
| Drug therapy | | | | | | |
| Receiving statin prescription | 3.0 | 2.90, 3.01 | <.0001 | 1.01 | .96, 1.06 | .71 |
| Receiving ACE inhibitor prescription | 2.42 | 2.35, 2.50 | <.0001 | 1.19 | 1.12, 1.25 | <.0001 |
| Receiving oral antidiabetic agent prescription | .89 | .86, .92 | <.0001 | 1.19 | 1.13, 1.26 | <.0001 |
| Receiving insulin prescription | 1.34 | 1.30, 1.39 | <.0001 | 1.56 | 1.47, 1.66 | <.0001 |
| Receiving thrombocyte aggregation inhibitor prescription ^f | ND | ND | | .97 | .91, 1.03 | .26 |
| Intermediate outcomes (treatment targets achieved) | | | | | | |
| Achieving LDL cholesterol <100 mg/dL | 2.18 | 2.09, 2.27 | <.0001 | 1.12 | 1.06, 1.19 | .0002 |
| Achieving systolic blood pressure <130 mm Hg | 1.46 | 1.40, 1.52 | <.0001 | 1.06 | .996, 1.13 | .07 |
| Achieving diastolic blood pressure <80 mm Hg | 1.40 | 1.34, 1.45 | <.0001 | 1.07 | 1.01, 1.14 | .03 |
| Achieving A1C <7% | 1.37 | 1.33, 1.42 | <.0001 | .95 | .90, 1.0 | .051 |

A1C indicates glycosylated hemoglobin; ACE, angiotensin-converting enzyme; BMI, body mass index; CI, confidence interval; DMP, disease management program; LDL, low-density lipoprotein; ND, no data; OR, odds ratio.

^aOdds ratios (95% CIs) were obtained by multivariable, multilevel regression models that adjusted for patient case-mix (patient sex, age, BMI, and atherosclerotic disease) and for physician-level clustering.

^bAdjustments were made for patient case-mix (patient sex, age, BMI, atherosclerotic disease), secular trends, and physician-level clustering.

^cAn OR of >1 indicates the recent cohort was better than the previous cohort.

^dAn OR of >1 indicates DMP was better than non-DMP.

^eIn modeling the BMI target of <30 kg/m², no adjustments for BMI were made.

^fData on thrombocyte aggregation inhibitor prescription were not available for the previous cohort.

nificantly higher in the DMP group compared with the non-DMP group. The use of oral antidiabetic drugs decreased over time but was significantly higher in the DMP group. The use of insulin increased over time and was higher in the DMP group.

Mean total and LDL cholesterol concentrations decreased over time, while high-density lipoprotein (HDL) cholesterol and triglycerides increased. Total and LDL cholesterol concentrations were lower in the DMP patients, while there were no differences in mean HDL cholesterol and triglycerides. Mean systolic and diastolic blood pressure values decreased over time and were slightly (<1 mm Hg) but significantly lower in the DMP group. Mean A1C values decreased by 0.2 percentage points over time, but were not different between the DMP and non-DMP groups. These positive developments over time were observed despite a significant mean weight gain.

The proportion of patients achieving targets for LDL cholesterol, blood pressure, and A1C increased significantly over time and was slightly but significantly higher for LDL cholesterol in the DMP group compared with the non-DMP

group (27.7% vs 25.4%). The differences between DMP and non-DMP groups were not significant for systolic blood pressure and A1C targets, and just reached significance for diastolic blood pressure. **Figure 2** illustrates the proportions of patients reaching different targets for the 3 main intermediate outcomes.

Multivariable Analyses

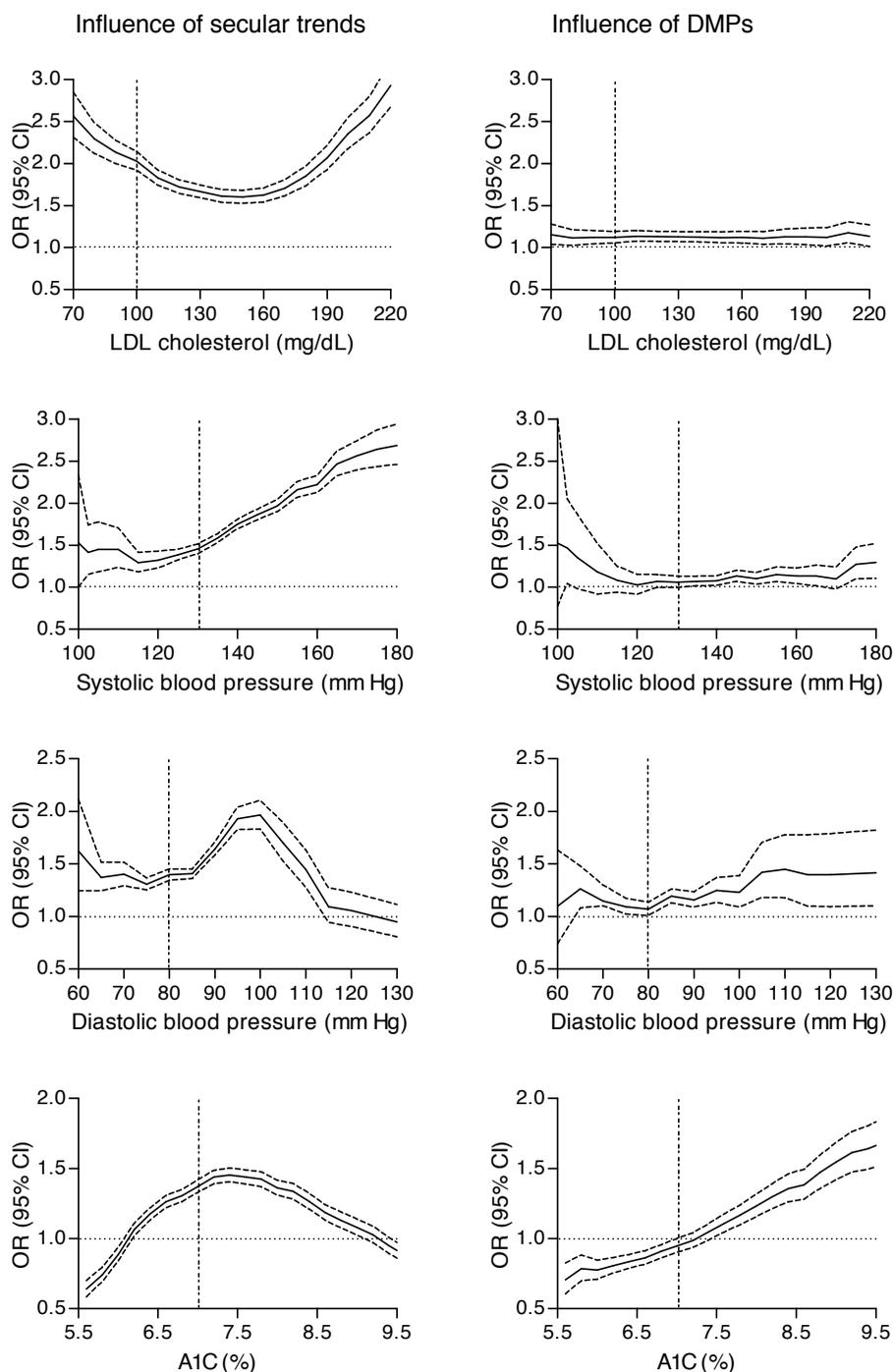
The results of the multivariable, multilevel analyses are shown in **Table 2**. We observed secular trends that showed improvements in most processes of care and intermediate outcome measures (more structured diabetes education, more determinations of lipid levels and blood pressure, more prescriptions of statins and ACE inhibitors, better achievement of all 3 treatment targets), but some parameters worsened (smoking frequency, BMI). Prescription rates for oral antidiabetic drugs decreased while the ones for insulin increased.

When comparing the outcomes between patients in DMPs with the outcomes of patients not in DMPs, signifi-

cant differences were observed. The differences in favor of the DMPs were seen in the odds of being a nonsmoker, receiving structured diabetes education, having blood pressure and A1C measured, and receiving prescriptions for ACE inhibitors, oral antidiabetic drugs, and insulin. Patients in DMPs were less likely to have a BMI of <30 kg/m². There were no differences between the 2 groups in having lipid levels determined and in receiving prescriptions for statins or thrombocyte aggregation inhibitors. There were only small but significant differences in achieving LDL cholesterol and diastolic blood pressure targets (OR 1.12 and 1.07, respectively), while there was no significant difference in achieving systolic blood pressure and A1C targets.

In Table 2, ORs for achieving the intermediate outcome targets of LDL cholesterol, systolic and diastolic blood pressure, and A1C were modeled for 1 specific target value only (ie, LDL cholesterol <100 mg/dL, systolic and diastolic blood pressure <130/80 mm Hg, A1C <7%). **Figure 3** shows these odds ratios modeled through a linear range of targets. The data show that time and DMPs influenced the association of intermediate outcomes and the respective ORs in different ways, depending on to which specific value the target was set.

Figure 3. Odds Ratios of Target Achievement for LDL Cholesterol, Blood Pressure, and A1C^a



A1C indicates glycosylated hemoglobin; CI, confidence interval; DMP, disease management program; LDL, low-density lipoprotein; OR, odds ratio. The vertical lines indicate the target levels used in multivariable analyses in Table 2. The dashed lines indicate upper and lower CIs.

^aTarget values were modeled through their whole range. The graphs on the left indicate the influence of time (previous vs recent cohort) and those on the right indicate the influence of DMPs. If lower 95% CIs are above the horizontal dotted line, this indicates "positive secular trend" or "DMP better" in achieving the targets. Note the different shapes of the curves. For example, DMPs have a robust small but significant influence on achieving LDL cholesterol targets (top right panel), irrespective of lower or higher targets (horizontal line). Conversely, DMPs only have a significant influence on achieving A1C targets (bottom right panel) if these are set to above approximately 75% (positive slope).

Further Analyses

We performed further multivariable analyses in order to investigate the influence of certain processes of care on intermediate outcomes—namely, the influence of structured education on achieving the A1C target and of statin prescription on achieving the LDL cholesterol target. When the full multilevel model for achieving the target A1C of <7% was additionally adjusted for structured diabetes education, the influence of DMPs became nonsignificant (OR .97, 95% CI .92, 1.02; $P = .19$). Structured diabetes education was even found to slightly decrease the odds of achieving A1C target values (OR .95, 95% CI .92, .98; $P = .003$). The beneficial influence of DMPs on achieving LDL cholesterol targets of <100 mg/dL (OR 1.12, 95% CI 1.06, 1.19; $P = .0002$) was not influenced when the model was further adjusted for statin prescription, but statin prescription by itself independently improved the odds of achieving the target (OR 1.25, 95% CI 1.20, 1.30; $P < .0001$).

DISCUSSION

Our results show that quality of diabetes care improved substantially between 2003 and 2007 as a secular trend. Disease management programs as implemented in Germany, however, improved processes of care but only 1 intermediate outcome: LDL cholesterol target achievement.

The 2 risk factors that worsened over this time period were lifestyle related (ie, smoking, BMI), which probably reflects the widely reported worldwide increase in prevalence of both obesity²² and tobacco use.²³ Our finding of a general improvement of diabetes care over time is in accordance with the findings of a Norwegian study, which showed improvement in processes of care and risk factor control in patients with type 2 diabetes between 1995 and 2005.²⁴ These authors found an improvement in statin prescription rates as well as in achieving target values of LDL cholesterol, systolic and diastolic blood pressure, and A1C despite weight gain. Smoking trends were not examined. A study from England also found an improvement in the quality of care of patients with diabetes between the years 1998 and 2003.²⁵ There were improvements in cholesterol and blood pressure control and a small, nonsignificant improvement in glycemic control. Smoking and BMI data were not reported. In the United States, there was a decline in A1C from 7.8% to 7.2% between 1999 and 2004.²⁶

While the reasons for these improvements are probably multifactorial, one factor that could have played a role is the introduction of DMPs in various countries. However, DMPs differ in their specific approaches in the various countries where implemented, ranging from Nepal²⁷ to the United States.²⁸ It should be noted, however, that Germany is the

only country that has implemented nationwide primary care–based and physician-sustained DMPs, which differ substantially from “classic” DMPs in the United States. Namely, they combine the application of sophisticated information technology systems and intensive data collection while also drawing on physicians’ first-hand knowledge of, and personal relationship with, their patients.²⁹ Some of the reasons for introducing DMPs in Germany were to improve quality and solve efficiency problems in the treatment of chronic diseases, as well as to promote competition among healthcare providers.^{7,30} The essential content of DMPs is determined by a national expert group and its recommendations are mandatory for any contract between insurers and providers.³¹

The DMPs were also intended to provide financial incentives to physicians to care for patients with chronic diseases. Health insurance companies with a high share of DMP participants received higher compensation per DMP patient based on a risk structure compensation scheme. If health insurance companies evaluate a system that provides them with increased profits, an in-built conflict of interest could be in play. In this context, although the benefits derived from DMPs have been widely purported,^{10,29} there is a relative paucity of independent scientific evidence supporting these claims. A cluster-randomized trial sponsored by a health insurance company³² concluded that patients in DMPs have decreased mortality rates, which, however, cannot be attributed to the DMPs.³³ A health economic study (in which only 149 patients could be evaluated) concluded that quality of care in patients with diabetes improved since the introduction of DMPs.³⁴ This latter study was also sponsored by the largest German health insurance company. However, Knight et al³⁵ performed a systematic review of diabetes DMPs (24 studies involving 3720 patients) and found that DMPs did not improve blood pressure or LDL cholesterol levels, but they were associated with a 0.5 percentage point decrease in average A1C levels. Moreover, a large retrospective cohort study from the United Kingdom (N = 42,032) recently examined the management of diabetes between 2001 and 2007 and assessed the influence of the introduction of DMPs.³⁶ They reported, in accordance with our findings, that over time there was improvement in processes of care and in achieving intermediate outcomes. Interestingly, they also observed that after the introduction of DMPs the existing trends of improvement in glycemic control, cholesterol levels, and blood pressure were attenuated.

To our knowledge, the present study is one of the largest studies to date (N = 25,084) analyzing the effect of DMPs in processes of care and in risk factor management (intermediate outcomes). Regarding processes of care, there were clear differences between patients managed in DMPs and those not managed in DMPs. The former had higher likelihoods of

being nonsmokers, receiving structured diabetes education, having their blood pressure and A1C measured, and receiving an ACE inhibitor or hypoglycemic agents. Regarding risk factor control, the DMP patients were 12% more likely to achieve LDL cholesterol target values and 7% more likely (borderline significant) to reach diastolic blood pressure target values. Interestingly, while patients in DMPs received more ACE inhibitors, there was no difference in the statin prescription rates between the 2 groups. Increased compliance and/or dose adjustments in patients in DMPs may explain this observation. Our analyses indicate, however, that a single therapeutic measure, the prescription of statins, improved intermediate outcomes independently of DMPs.

What are the health implications of these results? Regarding LDL cholesterol, it could be argued that the observed size of differences in concentrations achieved (3 mg/dL) is too small to be clinically relevant. However, it has been shown that a 1 mg/dL change in LDL cholesterol decreases the risk for CHD by about 1%.³⁷ Regarding blood pressure, the DMP patients were slightly more likely to achieve diastolic blood pressure target values and were equally likely to achieve systolic targets. Systolic blood pressure has been shown to be a clearly better indicator of cardiovascular risk than diastolic blood pressure.³⁸⁻⁴¹ Moreover, recent evidence in patients with type 2 diabetes from the ADVANCE cohort has found that regarding blood pressure indices, systolic blood pressure is the most effective and diastolic blood pressure the least effective determinant of cardiovascular outcomes.⁴²

Prescription of ACE inhibitors, but not of statins or thrombocyte aggregation inhibitors, was more common in patients in DMPs. Use of antihypertensive agents, lipid-lowering drugs, and acetylsalicylic acid reduces the risk of cardiovascular events by 25%, and the results appear to be additive.^{42,43} Data from the United Kingdom Prospective Diabetes Study have shown that statins and antihypertensive drugs have the largest effect in reducing cardiovascular risk, with hypoglycemic agents and acetylsalicylic acid being the next most important interventions.⁴⁴ Therefore, the significantly higher prescription rate for ACE inhibitors in DMPs may be of clinical relevance regarding cardiovascular outcomes.

There was no difference in achieving A1C target values between the DMP and non-DMP groups. Furthermore, receiving structured diabetes education offered no benefit in achieving glycemic targets. This finding is not surprising, considering the fact that although some studies showed a small positive effect of patient education on A1C values,⁴⁵ many (including a systematic Cochrane review) have not.^{46,47}

As shown by Figure 3, the question of whether secular trends or DMPs improve outcomes depends on which target value is chosen as the outcome measure. For example, DMPs

have a small but significant linear influence on achieving LDL cholesterol targets, no matter whether these targets are set to <100 mg/dL or to <130 mg/dL or even higher values. On the other hand, DMPs only have a significant influence on achieving A1C targets if they are set to above approximately 7.5%. Lower targets are even adversely influenced by DMPs.

Relatively early on, critics in Germany pointed to the fact that the introduction of DMPs would mainly provide an incentive for health insurance companies to enroll as many chronically ill patients as possible, without necessarily succeeding in improving their care.⁴⁸ Rigorously designed studies to investigate the effectiveness of diabetes DMPs are missing. It seems that the "time window" that could (and should) have been used to perform such studies is closed now for political reasons. The present study shows that there have been substantial improvements in type 2 diabetes quality of care in Germany since 2002 and that DMPs improve some processes of care. With respect to intermediate outcomes, they offer an increased likelihood for achieving LDL cholesterol target values, but only minimal improvements in glycemic and blood pressure control. The clinical relevance of these differences remains to be proved.

Limitations

Potential limitations of the present study are its cross-sectional design and selection bias at the point of care (regarding which subjects would be included in a DMP or not). Patients enrolled in DMPs may differ from patients not enrolled in DMPs for several reasons. The patients not enrolled in DMPs may not have the willingness or motivation to actively pursue treatment goals. On the other hand, their diabetes may be well controlled with few comorbidities, so they do not see much benefit in enrolling in a DMP. These 2 factors would have opposing effects on the relationship between DMPs and the outcomes examined in the current study. For example, if individuals with poorly controlled diabetes are primarily enrolled, DMPs might appear to result in decreased attainment of intermediate outcome goals. Conversely, if more motivated individuals are enrolled in DMPs, then DMPs might appear to result in increased attainment of process of care measures, greater medication use, and better intermediate outcomes. Therefore, it is impossible to say in what direction the estimates are biased. Despite adjusting for sex, age, BMI, and atherosclerotic disease, there was likely some residual confounding. However, a study in Germany found that subjects who are less ill are not overrepresented in the DMPs and that there is only a nominal social strata gradient between participants and nonparticipants.³³ Moreover, another study found no difference in age, sex, level of education, German language skills, or diabetes duration between enrollees and nonenrollees.⁴⁹

We were unable to adjust for certain patient factors such as levels of physical activity and socioeconomic or educational background, which may have been confounders in the relationship between our covariates and outcome measures. Another limitation is the lack of information regarding the length of an individual patient's participation in a DMP (short time periods might have prevented beneficial effects from becoming detectable). Strengths of the study are its large sample size, the multilevel modeling approach, and the fact that the investigators have no relevant conflicts of interest (they are working neither for health insurance companies, nor for associations of statutory health insurance physicians, nor as primary care providers).

CONCLUSIONS

In a rapidly changing healthcare system, changes in quality of care cannot be attributed to any single intervention. Nevertheless, the design and results of the present study suggest that secular trends exerted a much greater influence than the DMPs during the last few years. Improvement in care may be due to a generally better translation of guidelines into everyday practice, since most diabetes guidelines now recommend an intensified intervention targeting all known modifiable risk factors with ambitious treatment goals. In summary, the present study provides evidence that the utility of type 2 diabetes DMPs as implemented in Germany is limited.

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