German Diabetes Disease Management Programs Are Appropriate for Restructuring Care According to the Chronic Care Model

An evaluation with the Patient Assessment of Chronic Illness Care instrument

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OBJECTIVE — With the introduction of diabetes disease management programs (DMPs) in Germany, there is a necessity to evaluate whether patients receive care that is congruent to the Chronic Care Model (CCM) and evidence-based behavioral counseling. We examined differences as perceived and experienced by patients with type 2 diabetes between those enrolled in a DMP compared with patients receiving usual care in two federal states of Germany.

RESEARCH DESIGN AND METHODS — A random, heterogeneous sample of 3,546 patients (59.3% female) received a mailed questionnaire from their regional health fund, including the German version of the Patient Assessment of Chonic Illness Care (PACIC) instrument, which had additional items for behavioral advice (5A). Two weeks later, a general reminder was sent out.

RESULTS — A total of 1,532 questionnaires were returned (response rate 42.2%), and valid data could be obtained for 1,399 patients. Mean age of responders was 70.3 years, of which 53.6% were female. Overall, patients enrolled in a DMP scored significantly higher (3.21 of a possible 5) than patients not enrolled in a DMP (2.86) ($P < 0.001$). Significant differences in the same direction were found on all five subscales of the PACIC. For the 5A scales, similar differences were found for all five subscales plus the sum score ($P < 0.001$; mean for DMP = 3.08, mean for non-DMP = 2.78).

CONCLUSIONS — DMPs, as currently established in primary care in Germany, may impact provided care significantly. The changes in daily practice that have been induced by the DMPs are recognized by patients as care that is more structured and that to a larger extent reflects the core elements of the CCM and evidence-based counseling compared with usual care.

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I mproving the quality of care for patients with type 2 diabetes and other chronic conditions is an important aim of health policy and providers in many countries throughout the world. In countries like the U.S., disease management programs (DMPs), defined as structured, multifaceted, systematic approaches to provide better care (1), have been introduced by a vast number of "players" and

providers with different approaches for >20 years (2), showing small to modest results.

In Germany, with its statutory health insurance system insuring ~90% of the population, DMPs were introduced nationwide in 2003 on the basis of a new legislation that aimed to improve quality of care and to foster competition among health insurance providers (3,4). In contrast to the U.S., the core content of a DMP in Germany (e.g., evidence-based clinical guidelines, basic dataset, quality indicators, transfer between different levels of care, provision of feedback, recall for patients, etc.) is defined by a national expert group, and its recommendations are compulsory for contracts between insurers and providers, although there are smaller differences in detail (e.g., type of feedback report, remuneration, etc.) among programs of different contracting partners. Family practitioners (general practitioners, family physicians, and internists) in small- to medium-size practices have a central role in coordinating the care of enrolled patients. Currently, it is unclear how good family practitioners in private practices can fulfill this role and if they can make a difference for patients enrolled in a DMP. It also would be interesting to know if they provide similar quality of care to that of practitioners in a managed-care environment or in centrally coordinated programs like those existing in many countries.

At the time of their development and introduction, the national DMPs were heavily opposed by the medical profession (5,6) under arguments such as their being "cookbook medicine" providing "suboptimal care" or that recommendations that were given are not new but are already fully implemented into routine daily practice (7). The DMP for type 2 diabetes was first introduced in 2003. By mid-2007, ~2.3 million patients with

type 2 diabetes (~50% of the estimated number of patients in the population) and 30,300 family practices (~65%) were actively enrolled (personal communication, S. Hilfer). Still, a reasonable number of physicians refuse to take part. Enrollment of a patient for the program requires prior enrollment of the family physicians of the practice. If the doctors refuse to do that, patients have to change to another practice if they want to participate in the DMP. This might be a major barrier for the majority of elderly patients with chronic diseases such as diabetes, for whom continuity of care plays an important role (8). Assuming that the rationale of the programs (e.g., evidence-based, structured care, focused on patient activation) is not questionable and favors better outcomes, it should be expected that family physicians who do not participate in the program provide lower quality of care for their patients than those who are enrolled.

Unfortunately, the statutory nationwide evaluation of the DMP for type 2 diabetes does not compare providers or patients who are enrolled with those who are not (9). Because of the short timeframe in which it was introduced, baseline measurements were not taken. Fortunately in two areas of Germany, in a larger study, the Evaluation of a Large-Scale Implementation of Disease Management Programs (ELSID), for patients with type 2 diabetes (10), a cross-sectional approach and a cluster-randomized controlled trial intervention to optimize the implementation of the DMP are combined. In this study, a total sample of 20,625 patients in two federal states allows a more systematic comparison of patients and practices not enrolled or enrolled on the basis of clinical data, sickfund claims data, and patient experiences.

Meanwhile, more comprehensive frameworks such as the Chronic Care Model (CCM) receive widespread attention (11,12), and elements of this model that may be most effective in improving care processes, costs, and clinical outcomes have been recently evaluated (13,14). The Patient Assessment of Chronic Illness Care (PACIC) instrument has been proven to be a reliable and valid tool (15) to measure quality of care according to the CCM and patient motivation according to the "5A" principles, with the PACIC-5A regarding different chronic diseases such as diabetes (16–19). It addresses from a patient's perspective and experience to what extent provided care

complies with the CCM. Until now, it was unknown how different types of care are experienced by patients and to what extend they adhere to the CCM. Since the aim of the DMPs is to structure care according to core elements similar to those of the CCM, we hypothesized that enrolled patients would achieve higher scores on the PACIC, suggesting better quality of care.

RESEARCH DESIGN AND METHODS

For this study, we drew a random sample of 3,546 patients (59.3% female) out of the total sample ($n = 20,625$, 59.2% female) of the ELSID study, which is performed in two different German federal states, Rheinland-Pfalz and Sachsen-Anhalt. The total sample is, based on routine claims data, representative of the insured patients with type 2 diabetes of one health fund and already treated by a family practitioner. The study protocol for the ELSID study and the inclusion criteria for patients were registered and published previously (10). The protocols for the ELSID study and for this survey were both fully approved by the ethics committee of the University of Heidelberg Medical Faculty.

In November 2006, all 3,546 patients received mail with a cover letter directly from their health insurance provider (all patients where insured by one large statutory regional health care fund, which covers ~40% of the population), including the questionnaire material labeled with a unique pseudonym for each patient and a postage-paid return envelope addressed to the study center. Two weeks later, all patients received a general reminder letter (without questionnaire) from the health fund again, regardless of whether they had sent their questionnaire back in the meanwhile or not. All patients could participate in the drawing of a prize of six times €250 (~$375) by sending in a separate postage-paid return envelope to the study center. The questionnaire included sociodemographic data, some self-reported health information (weight, height, smoking status, and a list of chronic conditions in the patients own words), and the validated and culturally adapted German version of the PACIC-5A. This version contained 26 items, including 6 items to produce subscales for behavioral counseling according to the U.S. Preventive Taskforce recommendations (16). The questions request that the patient evaluate the care they received from their family practitioner over the last 6 months with regard to several topics. The answers were given on a 5-point Likert scale (1 = almost never to 5 = almost always). After analysis, the PACIC-5A supplies a five-scale profile of scores related to different aspects of providing care according to the CCM: patient activation, delivery system/practice design, goal setting/tailoring, problem solving/contextual, and follow-up/coordination. Additionally, a sum score can be generated. Another scoring option provides five items on each of the 5A's subscales of assess, advise, agree, assist, and arrange. All single items and the structure of the scores for the original source version in English and the culturally adapted and validated German version are described elsewhere (17,18). All statistical analyses were conducted with SPSS version 15.0. Comparisons between groups were performed with the Wilcoxon-Mann-Whitney test for not–normally distributed data and the χ^2 test, respectively. The level of significance was $P = 0.05$.

RESULTS

Respondent characteristics
A total of 1,532 questionnaires were returned (response rate 42.2%), and valid data could be obtained for 1,399 patients. Figure 1 shows a flowchart for the conduct of the study and the response. For certain characteristics, a nonresponder analysis could be performed on the basis

Table 1—*Nonresponder analysis*

Patient characteristics	Responder	Nonresponder	Significance of difference (*P* value)
n	1,473*	2,073†	
Female subjects	787 (53.4)	1,337 (64.6)	<0.001
Mean age (years)	70.3 (69.86–70.74)	71.8 (71.4–72.2)	<0.001
Participation in DMP	909 (61.7)	934 (45.1)	<0.001

Data are mean (95% CI) or *n* (%). *The number of responders includes 74 questionnaires that were excluded from analysis. †The number of nonresponders includes 59 questionnaires that were sent back but not filled in.
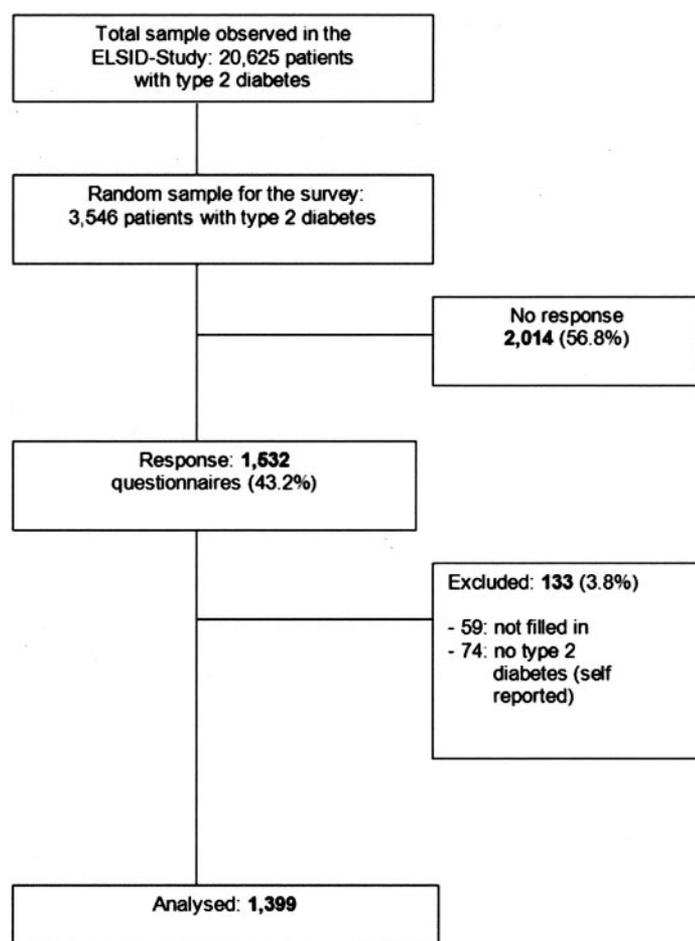
Figure 1—*Flowchart response.*

of claims data. On average, responders were younger and a higher proportion were male patients and patients participating in a DMP (Table 1).

Various characteristics of the study sample, separated in patients being enrolled in DMP (DMP group) and patients not enrolled (non-DMP group), are shown in Table 2. Of 1,399 included patients, 649 were male (46.4%) and 750 were female (53.6%). The mean age for the entire sample was (means ± SD) 70.3 ± 8.5 years. There were no significant differences for other sociodemographic characteristics, such as being married/living in partnership, lower education, and low to medium annual household income. The average number of other (comorbid) self-reported medical conditions (including hypertension, coronary heart disease, chronic heart failure, ulcer, asthma, bronchitis, cancer, osteoarthritis, and stroke) was 2.1 (minimum 0, maximum 8) within the total sample (Table 2). On average, the patients were enrolled since 26.8 ± 9.0 months into the DMP for type 2 diabetes.

PACIC scale
The average overall score on the PACIC items was 3.21 of a possible 5 for the patients enrolled in the DMP versus 2.86 for the non-DMP patients under the care of family practitioners not enrolled in the DMP. This difference was statistically significant ($P < 0.001$) (see Table 3). Differences in the same direction were found on all five subscales of the PACIC on the same level of significance, except for patient activation, in which $P = <0.05$. Nominally, the difference was greatest at the follow-up coordination scale (mean difference = 0.44) and lowest at the patient activation scale (mean difference = 0.17).

5A scoring
For the 5A scales, again significant differences were found for all five subscales plus the sum score ($P < 0.001$) (Table 3). The mean for the overall 5A summary scale was 3.08 of a possible 5 for the DMP patients versus a mean of 2.78 for the non-DMP patients. The highest mean differences were found for the "assist" subscale (mean difference = 0.39) and the lowest for the "agree" subscale (mean difference = 0.25).

CONCLUSIONS — Patients with type 2 diabetes enrolled in a disease management program were more likely to receive patient-centered, structured, and collaborative care according to the CCM. This large cross-sectional study demonstrates significant differences in the quality of care as assessed by the PACIC-5A instrument between patients enrolled in the national DMP and patients who are not enrolled. These differences were largest for follow-up/coordination of care, goal setting/tailoring, and for the problem-solving/contextual scale. Similar findings were made for the 5A subscales in which the largest differences in the same direction were found for assist, advise, and assess.

Compared with data for diabetic patients from a U.S. study (17), German patients not participating in a DMP fall short in receiving aspects of care on the sum

Table 2—*Patient characteristics*

Patient characteristics	DMP	Non-DMP	Significance of difference (*P* value)
n	865	534	
Mean age (years)	70.2 ± 8.3	70.5 ± 8.9	0.52
Female subjects	465 (53.8)	285 (53.4)	0.89
BMI (kg/m^2)	30.3 ± 5.8	30.3 ± 6.5	0.86
Smokers	68 (8.0)	49 (9.3)	0.39
Number of other chronic conditions	2.1 ± 1.3	2.1 ± 2.1	0.51
Education (≤9 years)	612 (70.8)	386 (72.3)	0.54
Annual household income ≤€21,000 ($29,400)	722 (83.5)	435 (81.5)	0.34
Married/living in partnership	568 (65.7)	336 (62.9)	0.51

Data are means ± SD or *n* (%).

Table 3—*Results for overall PACIC scale, 5A scoring overall scale, and all subscales and differences between DMP and non-DMP patients*

Scale	DMP	Non-DMP	Significance of difference (*P* value)
Overall PACIC score	3.26 ± 0.9 (3.14–3.27)	2.86 ± 0.9 (2.78–2.94)	<0.001
Patient activation	3.26 ± 1.2 (3.18–3.34)	3.09 ± 1.2 (2.98–3.19)	<0.05
Delivery system/practice design	3.52 ± 0.9 (3.46–3.58)	3.29 ± 0.9 (3.21–3.37)	<0.001
Goal setting/tailoring	2.91 ± 1.1 (2.83–2.98)	2.50 ± 1.1 (2.40–2.59)	<0.001
Problem solving/contextual	3.39 ± 1.2 (3.31–3.47)	3.04 ± 1.2 (2.93–3.14)	<0.001
Follow-up/coordination	3.13 ± 1.1 (3.06–3.21)	2.70 ± 1.1 (2.60–2.79)	<0.001
Overall 5A score	3.08 ± 1.0 (3.02–3.15)	2.78 ± 1.0 (2.70–2.86)	<0.001
Assess	3.26 ± 1.1 (3.18–3.33)	2.91 ± 1.1 (2.81–3.00)	<0.001
Agree	3.24 ± 1.1 (3.17–3.32)	2.99 ± 1.1 (2.89–3.09)	<0.001
Advise	3.32 ± 0.9 (3.25–3.38)	2.95 ± 1.0 (2.86–3.04)	<0.001
Assist	3.21 ± 1.1 (3.13–3.28)	2.82 ± 1.1 (2.72–2.91)	<0.001
Arrange	2.87 ± 1.0 (2.80–2.93)	2.55 ± 1.0 (2.46–2.64)	<0.001

Data are means ± SD (95% CI).

score and all subscales of the PACIC and the 5A subscales. For example, on the overall PACIC score, the patients scored 2.7 vs. 3.2 in the U.S. study. In the U.S. study, patients scored, on average, 3.6 for "patient activation" (our study: 3.1), 3.5 for "delivery system/practice design" (our study: 3.3), 3.0 for "goal setting/tailoring" (our study: 2.5), 2.9 for "follow-up/coordination" (our study: 2.7), and 3.4 for "problem solving/contextual" (our study: 3.0). This may be due to the older age (our patients were, on average, 6.3 years older) and the higher number of comorbid conditions in our sample and to the fact that our patients in the non-DMP group received care in routine practices versus selected practices as in the sample Glasgow et al. (19) draws from for their validation study. Nevertheless, as in the U.S. study, patients enrolled in the DMP receive better care, as measured on the subscales for follow-up/coordination and similar care on all other subscales, including the 5A's. In a different study, with arthritis patients in Germany, we found even lower scores for patients at similar age in the control arm. This finding might be interpreted as some external validation, since care for patients with arthritis appears to be less structured because of the lack of clear recommendations for management in primary care versus for diabetes, and therefore lower scores on the PACIC-5A can be expected.

Our results have to be interpreted carefully. The return rate was modest, but a nonresponder analysis could be performed, showing that nonresponders were slightly older and that a higher proportion were female. Other studies (17,20) with the PACIC instrument yielded higher response rates with younger patients and by using more intense reminding procedures such as telephone calls. Other studies (21) with DMPs were more comparable. Response rates may be higher if sent out by a university department (22), but due to strict regulations for data protection we could not contact patients directly. BMI and percentage of smokers for patients participating in a DMP in our study are comparable with data from the U.S. (23) and from Germany (24). They only slightly differed from patients not participating in a DMP. Our analysis is cross-sectional, with patients from one major type of regional health fund, with a market share of >40% and a higher proportion of elderly insurants with chronic conditions than other insurers. Differences between the two groups of patients under investigation exist but do not allow any conclusion about a causal influence of the DMP. This may limit generalizability.

Strengths include the large and heterogeneous sample and the limitation of sampling bias within the patients of the health fund by means of clear selection criteria based on existing routine claims data and the draw of a random sample out of a very large representative sample of >20,000 patients with type 2 diabetes. Additionally, patients were not specifically informed that the aim of the study was to evaluate a DMP (which may have distorted results, as DMPs are still under political or public debate from time to time) but were told it was to evaluate the actual care they receive from their family practitioner.

In conclusion, our results suggest that DMPs for diabetes, as currently established in primary care in Germany, may impact provided care significantly. The changes in daily practice that have been induced by the DMPs are recognized by patients as care that is more structured and that reflects the core elements of the CCM to a larger extent than usual care. In the perception of patients, these differences exist and they may very well matter in terms of influencing clinical and economic outcomes (14). What makes this finding particularly interesting is that prior studies evaluating the implementation of CCM elements assessed provider structures or addressed process parameters. To our knowledge, this is the first larger study assessing different types of care (DMP versus non-DMP) and accordance of care with the CCM from a patients' perspective with the PACIC-5A instrument.

Our findings have to be completed later by the results of the final evaluation of the ELSID study. Of course it will be important to see if clinical parameters will improve in the DMP group. Nevertheless, these results might yield additional insight to the ongoing discussion on effective improvements of the quality of care for patients with chronic conditions.

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