Evaluation of a Diabetes Management System Based on Practice Guidelines, Integrated Care, and Continuous Quality Management in a Federal State of Germany

A population-based approach to health care research

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OBJECTIVE — The aim of this study was to evaluate the Saxon Diabetes Management Program (SDMP), which is based on integrated practice guidelines, shared care, and integrated quality management. The SDMP was implemented into diabetes contracts between health insurance providers, general practitioners (GPs), and diabetes specialized practitioners (DSPs) unified in the Saxon association of Statutory Health Insurance Physicians.

RESEARCH DESIGN AND METHODS — The evaluation of the SDMP in Germany represents a real-world study by using clinical data collected from participating physicians. Between 2000 and 2002 all DSPs and about 75% of the GPs in Saxony participated. Finally, 291,771 patients were included in the SDMP. Cross-sectional data were evaluated at the beginning of 2000 (group A1) and at the end of 2002 (group A2). A subcohort of 105,204 patients was followed over a period of 3 years (group B).

RESULTS — The statewide implementation of the SDMP resulted in a change in therapeutic practice and in better cooperation. The median A1C at the time of referral to DSPs decreased from 8.5 to 7.5%, and so did the overall mean. At the end, 78 and 61% of group B achieved the targets for A1C and blood pressure, respectively, recommended by the guidelines compared with 69 and 50% at baseline. Patients with poorly controlled diabetes benefited the most. Preexisting regional differences were aligned.

CONCLUSIONS — Integrated care disease management with practicable integrated quality management including collaboration between GPs and specialist services is a significant innovation in chronic care management and an efficient way to improve diabetes care continuously.

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Abbreviations: DSP, diabetes specialized practitioner; GP, general practitioner; OAD, oral antidiabetic drug; SDMP, Saxon Diabetes Management Program.

The growing interest in evidence-based medicine and outcome and a commitment to integrated care across primary and secondary care sectors all contribute to making disease management an attractive idea (1). The disease management process (1) integrates guideline application, integrated care, continuous quality improvement (2), and patient education (3), but its effectiveness is largely untested, making evaluation essential.

There is evidence of regional variations in diabetes management in different primary care settings within the same country (4–6). Several structural barriers for integrated care at multiple care levels affect the delivery of high-quality diabetes management (7,8). These barriers are ascribed to behavioral aspects of patients and health care providers (e.g., unawareness of guidelines) or may be system oriented (e.g., fragmentation of the care delivery system) (7,9,10). Implementing managed care structures with a strict focus on integrated care (11–13) may reduce these barriers (14) while keeping costs under control (15).

In 1989 the implementation of the St. Vincent Declaration required the establishment of organized management structures in Europe to improve diabetes care and to reduce the incidence of diabetes complications (16,17). Effective and efficient cooperative management structures for diabetes treatment with adequate quality control were crucial because of the complexity of diabetes care. In 1991, Saxon diabetes experts developed the first health care model (diabetes agreement) with the aim of improving diabetes care by establishing diabetes specialist practices (DSPs) (18). In 1994–1995, the second diabetes agreement was set up, including quality workshops of GPs, addressing quality management in three cities in the three different administrative

Table 1—*Change of therapy between the first data collection period and Q4–2002 in three different administrative regions of Saxony*

Patient and therapy characteristics	Observation period							
	Observation 1994–1996				Q4–2002			
	Region 1	Region 2	Region 3	Total	Region 1	Region 2	Region 3	Total
Patients (*n*)	280	558	288	1,126	72,826	87,889	65,710	226,425
Physicians (*n*)	15	26	13	54	673	781	574	2,028
Age of patients (years)	67	68	68	68	68	68	67	68
A1C (%)	8.4 ± 1.8	8.0 ± 1.7	7.4 ± 1.4	7.9 ± 1.7	6.8 ± 1.2	6.8 ± 1.2	6.6 ± 1.1	6.8 ± 1.1
Diet alone (%)	20	36	29	30	33	34	32	33
OADs (%)	60	58	53	57	41	40	41	41
OADs + insulin (%)	17	4	8	9	15	12	11	13
CT (%)	3	2	10	4				
ICT (%)	0	0	0	0	11	13	16	13

Data are means ± SD unless otherwise indicated. CT, conventional insulin therapy; ICT, intensified conventional insulin therapy; Q4–2002, last quarter in 2002.

regions of Saxony. The evaluation of the quality workshops showed significant regional differences of care quality (Table 1), and a survey completed in 1996 revealed that this care model could not be implemented statewide. Consequently, in 1997 the Saxon Diabetes Committee published transdisciplinary guidelines that also defined network structures (19).

Subsequently, the Saxon Diabetes Management Program (SDMP) was developed, preceded by a pilot study (EVA study) of the Saxon Care Model (14). The primary aim was to gain access to the whole diabetic population statewide by encouraging GPs and DSPs to participate in the SDMP. Consequently, it was necessary to establish a management program that improved the cooperation between the GPs and the DSPs and required only minimal input for documentation, quality management, and administration. The four core elements of the SDMP according to Hunter and Fairfield (1) were *1*) integrated practice guidelines, *2*) integrated care structures, *3*) integrated quality management, and *4*) patient education programs. The aim of the present analysis was to elaborate on the experiences gained during the implementation and evaluation of the integrated SDMP.

RESEARCH DESIGN AND METHODS

Concept of the SDMP

***1*) Integrated practice guidelines.** The practice guidelines were developed by the Saxon Diabetes Committee, a professional, multidisciplinary body belonging to the Chamber of Physicians and representing the different levels of diabetes care (GPs, DSPs, and inpatient health care) (19). These knowledge-based consensus guidelines were sent to all GPs and diabetes specialists in Saxony before the start of the SDMP. These guidelines defined therapy targets and criteria for timely referral of patients to DSPs among others.

***2*) Integrated diabetes management structure.** The aim was to establish an intersectoral multidisciplinary health management system (between GPs and DSPs). Based on the guidelines, an agreement was reached between health insurance companies and the Saxon Association of Statutory Health Insurance Physicians on behalf of GPs and DSPs. GPs were to treat patients at low risk for complications. The patients should be referred to DSPs when A1C and/or the blood pressure exceeded 7.5% and 140/90 mmHg, respectively, twice in a sequence, if the therapeutic potential of the GP was exhausted. This was just a recommendation but not a directive because it was not our intention to establish bureaucratic barriers and pressure. After a period of three quarters the patients should be referred back to the GP. If these risk indicators could not be improved, the DSP was requested to send the patient to a diabetes clinic.

***3*) Integrated quality management as a basis for evaluation.** The quality management system of SDMP comprised two strategies:

- Incentives for patient coordination and data documentation by GPs (6 €/patient) and additional incentives for outpatient care in the DSPs, avoiding the need for inpatient treatment in the hospital
- Continuous quality management and training of GPs performed by certified DSPs.

For the incentive-based system the participating physicians had to collect medical data and to complete a care report form (CRF) once at baseline and thereafter in quarterly intervals. Apart from the patient identification and health insurance identification number, the following information was collected: year of birth, sex, type and duration of diabetes, and current therapy. During follow-up, outcome indicators such as A1C, blood pressure, and hospitalizations were recorded. Furthermore, physicians maintaining computer-aided patient records were asked to report every change of therapy. Referral data could be extracted indirectly from the longitudinal documentation process.

The integrated system of continuous quality management comprised regular quality workshops (2–4 times a year) in which the regional DSPs discussed guidelines and international advances, as well as the results of the regular quality management together with the GPs. For this benchmarking, GPs and DSPs received quarterly quality reports based on the collected data and comparisons of outcome indicators among participating entities. The aim of the quality workshops was to improve overall patient care and to approach the target values by training/education of GPs. To keep costs and capacity of DSPs within limits the aim was to enhance the competence of the GPs beyond the increasing referral frequency to DSPs. Furthermore, the GPs should learn to recognize their limits. The outcome for the first priority was successful, achieved not only by improved cooperation but also, primarily, by improved communication.

***4*) Education: the patient factor.** The SDMP also included structured patient

education programs. For patients with poor diabetes control a reinforcement of the education program should be performed by the DSPs. Furthermore, all patients with newly diagnosed diabetes should attend a lifestyle education program at the local DSPs. For education of younger type 2 diabetic patients, an interactive patient-oriented program called MEDIAS, which is based on a patient empowerment and a patient self-management concept, was presented by certified DSPs. For elderly individuals a simple program called ZI-Program was recommended for use by GPs also (20).

Evaluation concept

The evaluation concept was performed as a real-world study. The observed target population consisted of all diabetic patients who received medical care at SDMP-participating practices: 291,771 diabetic patients. Saxony had a reference population of about 4.38 million between 2000 and 2002. Thus, about 6.7% of the general Saxon population was involved in the study. In comparison, the estimated diabetes prevalence was 6–8% nationwide.

The continuous evaluation consisted of several cross-sectional surveys at baseline, i.e., in the first quarter of 2000 (Q1–2000: group A1) and then in quarterly intervals between January 2000 and December 2002. The last survey commenced in the last quarter of 2002 (Q4–2002: group A2). A subgroup of 105,204 patients was followed up over 3 years (follow-up: group B). The cohort consisted of patients with a complete documentation of A1C and also of blood pressure for the first quarter of 2000 as well as the fourth quarter of 2002.

The mean ± SD age and duration of diabetes were 67.7 ± 12.2 and 7.7 ± 7.2 years, respectively, in group A1 and 68.5 ± 12.3 and 8.3 ± 7.2 years, respectively, in group A2. At baseline, age and duration of diabetes in the cohort (group B) were similar to those in the first survey (group A1): initially 67.5 ± 11.4 and 7.9 ± 7.3 years, respectively, but increased to 70.3 ± 11.4 and 10.7 ± 7.3 years, respectively, during the follow-up.

The collected data were sent to the data management center at the Institute for Medical Informatics and Biometrics of the Technical University of Dresden. A1C and blood pressure were monitored as quality indicators of diabetes care. The cutoffs for high quality in diabetes care according to the guidelines were A1C level ≤6.5% and blood pressure ≤130/80 mmHg and for acceptable quality of care were A1C level ≤7.5% and blood pressure ≤140/90 mmHg. Therapy data were only available from computer-aided practices (n = 226,425 patients).

A1C, blood pressure, and therapy data were compared with pooled data of 1,172 diabetic patients collected from 54 GPs in previous quality workshops between 1994 and 1996 (prebaseline). Another previous data pool of all DSPs (n = 59) included data of patients who were referred for the first time to DSPs between Q3- and Q4–1996 (also prebaseline).

In 2000, the quality of the SDMP was monitored to exclude an over-reporting of good results. This was achieved by anonymous comparison of A1C values determined by three independent laboratories. Furthermore, a random sample of 292 individuals visiting pharmacies in different towns of Saxony was investigated for A1C values in 2000. These data were also compared with the evaluation outcome reported by the SDMP-participating physicians.

Laboratory and other methods

A1C values were measured in selected contracted laboratories certified by external German control management institutes (INSTANT or DGKC) over the whole observation period. Methods used were high-performance liquid chromatography (mainly BioRad Diamat) or immunoturbidimetry (mainly Roche Tinaquant) in a proportion of nearly 1:1. High-performance liquid chromatography was the reference method with the recommendation of an upper reference value of 6.1% compared with 6.0% for immunoturbidimetry.

External quality control checks were performed 2–4 times per year and covered the ranges 5.1–6.5% (decisive for diabetes) and 8.1–10.8%. There were no significant differences between the methods used or between the declared values and the results obtained by different laboratories. Changes between laboratories during the observation period were kept to a minimum, and the laboratories did not change their methods during the observation period.

Blood pressure was measured under standardized conditions by a physician or trained nurse. According to the guidelines, patients were categorized into good (≤130/80 mmHg), satisfactory (>130/80–140/90 mmHg), or poor (>140/90 mmHg) control. The worse systolic or diastolic blood pressure value was applied.

Data analysis

The statistical evaluation was performed using SPSS. Continuous variables are expressed as means ± SD. Because of the high number of patients included in relation to the estimated diabetes prevalence, it is assumed that nearly the entire diabetic population of Saxony was covered by this investigation. As the range of the confidence interval was ~0, a statistical inference for the cross-sectional surveys (groups A1 and A2) was not needed. For the follow-up of group B, a test statistic based on a normal distribution was used. Differences between mean values were tested by t test. The level of significance was defined as $\alpha = 0.001$.

RESULTS — A total of 202,293 patients were registered in the SDMP in the first quarter (Q1) of 2000 (group A1). The number increased to 291,771 in the last quarter (Q4) of 2002 (group A2).

A total of 471,150 patients were serviced in the SDMP at any time throughout the cumulative observation period. At the beginning, 1,864 GPs (~66% of all GPs in Saxony) and 87 DSPs (100%) participated in the program. At the end, the SDMP included 2,028 GPs (~75% of all GPs) and 102 DSPs (100%). A cohort (group B) of 105,204 patients, 56.3% women and 43.7% men with a median age of 68.7 years, could be followed up throughout the entire observation period.

Process quality

At the beginning, only 85% of the quarterly recommended A1C measurements and 87% of the blood pressure measurements were available. These rates increased toward the end, with 98 and 91% of completed data, respectively. The frequency of patient consultations differed only marginally between the surveys (cohort 0.94 ± 0.11 vs. cross-sectional 0.88 ± 0.19/quarter per patient). A1C values were independent of the number of consultations (observation period ≥1 year); with regular quarterly consultations the A1C was 6.61 ± 1.13% (n = 12,945). When consultations were performed 3–4 times per year the A1C was 6.57 ± 1.04% (n = 22,975), and with irregular consultations (<3/year) the A1C was 6.68 ± 0.97% (n = 362,641).

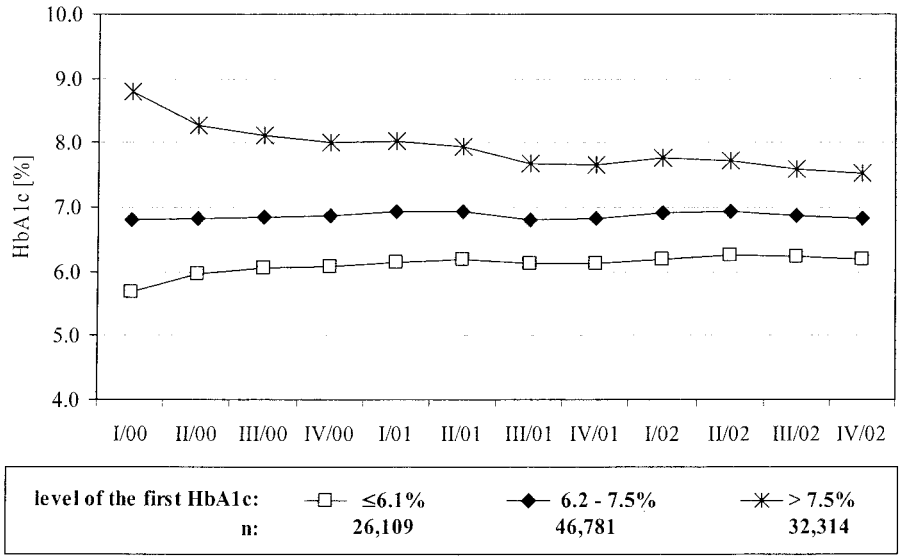

Figure 1—*Trends of quarterly mean A1C levels for patients with initial well- and poorly controlled diabetes, respectively, in the cohort (group B).*

Therapeutic outcome

Regional differences in therapy data are shown in Table 1. Results from earlier observations revealed significant regional differences between treatment patterns with a high prevalence of oral antidiabetic drugs (OADs) and a low percentage of dietary and/or insulin therapy. At the end of the SDMP, regional differences had equilibrated and the rate of OAD treatment had significantly decreased. The percentage of either dietary or insulin therapy, especially intensified conventional insulin therapy, increased (Table 1). Similarly, metabolic control (A1C) improved significantly (Table 1).

A1C and blood pressure

Of all patients of group B, 78% achieved the therapeutic targets according to the guidelines (A1C values ≤7.5%) at the end of the observation period compared with 69% at baseline. As many as 44% reduced their A1C values to <6.5% (vs. 39% at baseline). Of patients with poorly controlled diabetes treated exclusively by GPs, 60% achieved the target setting within the observation period, as did 55% of patients with very poor values who had to be referred to DSPs. Thus, the mean ± SD A1C decreased from 7.1 ± 1.4 to 6.9 ± 1.1% ($P < 0.001$) in group B and from 7.1 ± 1.4 to 6.8 ± 1.1% in group A, respectively. Regional differences had been reduced (Table 1). Furthermore, at the end of the investigation, 61% of group B achieved blood pressure values <140/90 mmHg compared with 50% at baseline. Thus, the blood pressure values decreased from 144 ± 16 to 141 ± 16 mmHg systolic and from 82 ± 9 to 81 ± 8 mmHg diastolic in group B ($P < 0.001$) and from 144 ± 17 to 140 ± 16 mmHg systolic and from 82 ± 9 to 81 ± 8 mmHg diastolic in group A.

Patients with poorly controlled diabetes (A1C >7.5%, $n = 32,314$) benefited the most, showing reductions from 8.8 ± 1.2 to 7.5 ± 1.2% after 3 years in group B ($P < 0.001$) (Fig. 1). The number of ineffectively treated patients with A1C values >7.5% or with blood pressure values >140/90 mmHg decreased significantly by ~50% within the observation period. By analyzing the combination of both parameters in group B, the relative number of patients at the highest risk (A1C >7.5% and blood pressure >140/90 mmHg) had been significantly reduced from 16.3 to 9.8% ($P < 0.001$) after the follow-up.

Of all patients, 24% were referred to DSPs at any time throughout the observation period or were treated in cooperation with DSPs. Although in 1996 the cutoff for first-time referral was 8.8 ± 2.3% A1C ($n = 682$, median 8.5%), it decreased to 7.8 ± 1.8% ($n = 5,636$, median 7.5%), similar to that required by the guidelines, at the end of 2002. There was an association between timely referral and optimal A1C and blood pressure. In region 3, with timely referral (cutoff 7.3 ± 1.6%) the mean ± SD A1C dropped from 7.0 ± 1.4 to 6.6 ± 1.1%. Because of higher cutoff at referral of 8.1 ± 1.7 and 7.8 ± 1.8% in regions 1 and 2, respectively, the A1C decreased to a lesser extent (from 7.2 ± 1.5 to 6.8 ± 1.2%). Even the blood pressure values of region 3 were lower than those of regions 1 and 2.

CONCLUSIONS— An integrated care system based on shared care responsibility was implemented as a diabetes management program statewide in Saxony (21). The SDMP included about 75% of the GPs and 100% of the DSPs of Saxony and ~90% or more of the Saxon diabetic population, indicating the acceptance of the SDMP by physicians and patients. First and foremost, the high and growing rate of participation was achieved by the minimal bureaucracy of the SDMP. This disease management model was characterized by a structured integrated care organization with minimal workload for quality management and coordination because it was outcome oriented. Analogous to the UK Prospective Diabetes Study, A1C and blood pressure served as quality indicators as a start in the SDMP.

The results of evaluation revealed a significant improvement in quality of diabetes care continuously. The SDMP led to a narrowing in regional differences in therapeutic management and outcome and to an approximation to targets as defined by the guidelines. At the end, 78% of group B achieved A1C values <7.5% compared with 69% at baseline. In 1994–1996 (prebaseline) only 47% of patients included in quality workshops of GPs achieved this target (22). More than half (54%) reduced their A1C values to well below 6.5% versus 39% at baseline. The number of ineffectively treated patients defined by A1C or blood pressure decreased significantly by ~50% within the observation period. Thus, the mean A1C values could be reduced from 7.1 ± 1.4 to 6.8 ± 1.1% within 3 years. Also the decreasing SD reflected a relevant improvement of care quality. Furthermore, a substantial improvement in blood pressure control was observed along with the improvement of A1C control: at the end, 61% of group B achieved blood pressure values lower than 140/90 mmHg compared with 50% at baseline. This improvement could be attributed to a shift in diabetes therapy characterized by a reduced application of OADs and increased frequency of diet and insulin therapy. The quality of therapy also improved with more frequent application of intensified conventional therapy. Patients with poorly controlled diabetes benefited the most at ~15% improvement in mean

A1C value within 3 years. We see this highly encouraging development as a result of integrated care owing to better communication and cooperation: GP training in quality workshops and/or patient referral to DSPs. In comparison, in the UK Prospective Diabetes Study, the median A1C of the intervention group was 7.0% at baseline and had increased continuously already after 1 year of follow-up (23,24). In other European countries, the following A1C values were reported on the basis of their national diabetes management: Italy 7.2 ± 1.6% in 2001 (25), France 7.6 ± 1.6% in 2001 (26), Belgium 8.0 ± 1.7% in 1999 (27), and Austria 8.1 ± 1.7% in 2001 (28). At the end of the SDMP, the risk of inefficient treatment was markedly reduced in about half of the patients. We observed that these patients were referred to the DSPs at an earlier metabolic stage than before. Thus, the earlier the patients were referred to DSPs, the better the results for A1C and blood pressure in the entire region.

The effectiveness of the SDMP in the real world can be attributed to the timely referral of patients to DSPs on the one hand and to the enhancement of competence of GPs by training in quality workshops by DSPs on the other, reflecting the feasibility of the integrated care approach without bureaucratic barriers. The novelty of the reported SDMP, however, is that DSPs and GPs as health care providers from different care levels collectively performed and discussed the quality management data, which was crucial for the success of the program: the collective discussion of results helped to break down barriers between the different care levels and to set up a self-supporting system to increase quality of care. We conclude that only integrated care structures with an integrated quality management system are sufficient.

Several limitations of the evaluation concept warrant consideration. Because this evaluation was conducted as a real-world study, it was not possible to compare the effects of the SDMP with a control group outside the SDMP. Patients could not be excluded from the SDMP, as the contract was mandatory statewide. To limit bias in relation to patients with newly diagnosed diabetes, in the cross-sectional survey the follow-up design was also used. The results obtained in the cross-sectional (A) and follow-up (B) design differed only marginally. Consequently, it can be concluded that bias due to subsequent inclusion of new cases of diabetes and of patients with newly diagnosed diabetes but also due to dropouts is negligible. The loss of follow-up was mainly a result of a change in the health insurance number that served as patient identification in the SDMP. Dropouts due to moves to another city or GPs not involved in the SDMP or to death or incomplete documentation in the last quarter of 2002 (based on 0.82 documentation/quarter per patient and 2% missing A1C values) also contributed to the loss of follow-up. Because the A1C values were independent of the number of consultations, it is assumed that compliance was not higher in the cohort than in the cross-sectional surveys. End point data would be nice to have but would not be so useful within the unfortunately short observation period of 3 years because of the limited running time of the diabetes contract.

To confirm their validity, documented data were checked to exclude an over-reporting of better results by participating physicians. Therefore, anonymous data from three different laboratories were compared with the evaluation outcome of year 2000. There were no significant differences in A1C levels between the laboratories and the evaluation outcome (7.0 ± 1.3 vs. 7.1 ± 1.3%, NS). Additionally, a random sample of 292 individuals visiting pharmacies in different towns in Saxony was investigated for A1C values (22). These data were also not significantly different from the evaluation outcome (7.0 ± 1.3 vs. 7.1 ± 1.3%, NS).

In summary, the strength of the SDMP is to provide a feasible, practical, and easy-to-handle tool for diabetes management for a general population. Therefore, the program allows establishment of long-term compliance of physicians. Although this program still showed marginal regional differences, it proved to be a valuable approach for increasing quality of care in an entire region or country.

In addition, we found that a coordinated, interdisciplinary, and integrated care setting was effective and efficient to reduce mean A1C and blood pressure continuously over time throughout a country. Therefore, it can be concluded that an integrated care disease management system, based on integrated practice guidelines implemented into an integrated care structure and a practicable integrated quality management, is an innovative way to improve diabetes care continuously throughout a country.

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