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The JEVIN trial: A population-based survey on the quality of diabetes care in Germany: 1994/1995 compared to 1989/1990

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Summary Since 1990 in most Eastern European countries health care systems have been decentralized or are undergoing the processes of decentralization. Increasingly, diabetic patients are no longer treated by diabetologists but by non-specialized physicians. During the same period structured treatment and teaching programmes have been introduced and health care is increasingly influenced by the St. Vincent declaration. To show the effect of these changes on the quality of diabetes care 90 % ($n = 244$) of all insulin-treated diabetic patients aged 16 to 60 years and living in the city of Jena (100247 inhabitants) were studied in 1994/1995. The results were compared with the baseline examination of 1989/1990 ($n = 190$). HbA_{1c} (HbA_{1c}/mean normal) in IDDM patients under specialized care was similar in 1994/1995 (1.54 ± 0.27, $n = 47$) to 1989/1990 (1.52 ± 0.31, $n = 131$, $p = 0.0018$), but higher under non-specialized care (1.71 ± 0.38, $n = 80$, $p = 0.0087$). In the total group of NIDDM patients there was no significant change in HbA_{1c} (1994/1995: 1.75 ± 0.4, $n = 117$, vs 1989/1990: 1.78 ± 0.4, $n = 59$, $p = 0.67$), but with a tendency to higher HbA_{1c} under non-specialized (1.81 ± 0.4, $n = 79$) compared to specialized care (1.66 ± 0.39, $n = 38$, $p = 0.06$). Incidence of severe hypoglycaemia (IDDM 0.13; NIDDM 0.04), ketoacidosis (0.02; 0.01) and the prevalence of nephropathy (21 %; 35 %) and neuropathy (24 %; 38 %) remained unchanged in comparison to 1989/1990, whereas there was an increase in the prevalence of diabetic retinopathy. Specialized care is mandatory for patients with IDDM. [Diabetologia (1997) 40: 1350–1357]

Keywords IDDM, NIDDM, population-based trial, HbA_{1c}, care quality.

Insulin-dependent (IDDM) and non-insulin-dependent (NIDDM) diabetes mellitus confer a high risk of developing diabetic late complications with the result of excess mortality and morbidity [1–5]. Up to the present, optimal quality of care and regular screening have been the most important factors for preventing late complications [6–10]. Most of the data available concerning quality management of diabetes have been derived from selected populations [11, 12].

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Abbreviations: NIDDM, Non-insulin-dependent diabetes mellitus; IDDM, insulin-dependent diabetes mellitus; 5-DTTP, 5-day diabetes treatment and teaching programme.

The purpose of this trial was to prove the implementation of the St. Vincent Declaration [13] in a non-selected population of diabetic patients in Germany with respect to the change in the health care from a centralized state system to a private one.

Subjects and methods

The JEVIN Trial (Jena's St. Vincent Trial), was started in 1989 in Jena (population in 1989: 105825), a town in the former German Democratic Republic [14]. The centralized diabetes care system was at that time intact. It was based on nationwide country and district diabetes care units and a diabetes registry [15]. At 31 December 1989 there were 3923 patients registered in Jena [14]. We examined 83 % ($n = 190$) of the 229 registered insulin-treated patients in the age group of 16 to 60 years [14, 16].

Table 1. Characteristics of the patients examined in 1989/1990 in comparison to 1994/1995

	IDDM			NIDDM		
	1989/1990	1994/1995	*p* value	1989/1990	1994/1995	*p* value
No. of patients	131	127		59	117	
Age (years)	37.0 ± 11.6	40.1 ± 12.0	0.064	53.0 ± 5.3	52.8 ± 6.4	0.581
Females (%)	39	36	0.879	59	54	0.568
Diabetes duration (years)	14.4 ± 11.0	16.8 ± 12.1	0.091	13.4 ± 4.8	12.3 ± 7.3	0.307
Body mass index (kg/m^2)	23.5 ± 2.7	24.2 ± 3.2	0.013	28.5 ± 4.8	28.6 ± 4.6	0.865
Current smokers (%)	43	32	0.0005	32	24	< 0.0001
Invalidity (%)	14	19	0.434	11	25	0.014
Systolic blood pressure (mm Hg)	135 ± 18	129 ± 16	0.0039	151 ± 28	137 ± 19	0.0003
Diastolic blood pressure (mm Hg)	85 ± 9	79 ± 9	< 0.0001	91 ± 13	82 ± 10	< 0.0001
Antihypertensive treatment (%)	20	25	0.393	53	47	0.569
Real hypertension[a] (%)	31	31	0.962	69	55	0.051

Mean normal HbA_{1c} in 1989/1990 4.15 % (SD 0.54), in 1994/1995 5.1 (SD 0.38). [a] BP ≥ 160 mm Hg systolic and/or ≥ 95 mm Hg diastolic and/or antihypertensive treatment

Since 1990, following the reunification of Germany, the health care system has been decentralized. Diabetes care units were mostly closed and diabetic patients were increasingly treated by non-specialized physicians. The central diabetes registry was discontinued. Ambulatory and inpatient care is sharply demarcated, with specialized physicians restricted from admitting patients without assignment of primary care physicians. Hospital care physicians are largely proscribed from providing outpatient care [17].

We identified the patients for the 5-year follow-up trial in 1994/1995 from four independent sources: 1) the previous diabetes registry from 1989; 2) the hospital database, because up to 1995 in Thuringia insulin treatment had only been started in hospitals; 3) the database of the university clinic outpatient department and 4) databases of family physicians. This method of using several sources guarantees 100 % identification of the target population by tracking each patient in at least two different sources.

Patients. In 1994/1995, we identified 271 insulin-treated diabetic patients aged 16 to 60 years and living in the city of Jena (population in 1995: 100242). Of these patients (IDDM $n = 127$, NIDDM $n = 117$, [18]) 90 % were examined by a physician. Since 1990 17 insulin-treated registered patients had died. Of the missing 27 patients, 10 refused to take part (3.7 %) and of the rest ($n = 16$, 6.3 %) we were either unable to trace the address or patients did not reply. The characteristics of the patients examined in 1994/1995 in comparison to 1989/1990 are shown in Table 1.

Intervention since 1989/1990. Following the reunification of Germany, with the change of the political system, there have been great shifts in socioeconomic factors. For example materials for blood glucose self-monitoring and insulin pens became available to everyone at all times. Additionally, the 'diabetic diet' [19, 20] has been liberalized [21].

Following the recommendations of the St. Vincent Declaration [13], structured treatment programmes for both IDDM and NIDDM were established [22–29]. Since 1989/1990 73 % of IDDM ($n = 93$) and 34 % of NIDDM patients ($n = 40$) have taken part in a 5-day structured diabetes treatment and teaching programme (5-DTTP) for intensified conventional insulin therapy [22]. Of the NIDDM patients 63 % ($n = 74$) have taken part in a 5-DTTP for type 2 diabetic patients with insulin therapy [23]. A total of 9 % ($n = 10$) of NIDDM patients took part in both 5-DTTPs [22, 23]. Only 27 % ($n = 34$) of IDDM patients and 11 % ($n = 13$) of NIDDM patients have not taken part in a DTTP up to the present. Until 1993, in the area of Jena, 56 % of general practitioners and physicians for internal medicine [16] took part in postgraduate training courses for the treatment of NIDDM.

Assessment of quality of care. To assess the quality of care the following investigations were performed: measurement of haemoglobin A_{1c} (HbA_{1c}, HPLC, Diamat, normal range: 4.4–5.9 % in 1994/1995, 3.1–5.2 % in 1989/1990, laboratory tests in 1989/1990 were performed in Aberdeen, the normal range of each method was assessed measuring 100 healthy subjects). For comparison of the two HbA_{1c} methods values were normed on the mean normal value (original HbA_{1c} value divided by the mean normal of the method), a method which guarantees good reliability as shown in the German Working Group for structured diabetes care. Self-monitoring and insulin dose adjustment were registered as frequency of tests/adjustments per week. The incidence of acute complications (severe hypoglycaemia, i.e. need for glucose or glucagon injection, ketoacidosis with hospitalization) were assessed by interview and controlled by comparison with emergency protocols and hospital records. Investigation of long-term diabetic complications was done by: 1) funduscopy through dilated pupils by an ophthalmologist. Retinopathy was staged as follows: normal, stage 1 (microaneurysms or soft exudates only), stage 2 (blot haemorrhages, hard exudates), stage 3 (proliferation and vitreous haemorrhages) [30]. 2) Screening for peripheral polyneuropathy according to Young et al. [4]. 3) Screening for nephropathy by measuring the urine albumin concentration (immunoturbidimetry 1989/1990, nephelometry 1994/1995, normal range: < 20 mg/l). For calculation the mean of three early morning urine tests within a period of 3 to 6 weeks was used. In the case of only two specimens being available the results were used only if both were in the normal range or both were elevated. Infected urine specimens (bacterial counts > 10^5/ml) were excluded.

Height and body weight were assessed with the patients wearing light clothing and without shoes. Blood pressure in the sitting position was measured after the patient had rested for 10 min by using a standard sphygmomanometer according to World Health Organisation (WHO) recommendations. Further socioeconomic data, quality of life and treatment satisfaction were assessed, and will be published in a forthcoming paper.

Statistical analysis was performed using Statgraph. All data are presented as mean ± SD. For comparisons the Student's *t*-test,

Table 2. Characteristics and results of diabetes therapy

	IDDM			NIDDM		
	1989/1990	1994/1995	*p* value	1989/1990	1994/1995	*p* value
No. of patients	131	127		59	117	
HbA_{1c}	6.3 ± 1.3[a] %	8.4 ± 1.8[b] %		7.4 ± 1.7[a] %	8.9 ± 2.1[b] %	
HbA_{1c}/mean normal HbA_{1c}	1.52 ± 0.31	1.65 ± 0.35	0.002	1.78 ± 0.31	1.75 ± 0.4	0.669
% of patients with HbA_{1c}						
≤ 1.2 normal mean	17	6	0.014	2	4	0.669
≤ 1.6 normal mean	41	54	0.076	63	39	0.001
Insulin therapy						
Duration (years)	14.4 ± 11.0	15.9 ± 12.1	0.283	5.1 ± 3.5	4.4 ± 4.3	0.337
Daily insulin dosage (IU)	37.7 ± 13.6	45.9 ± 21.7	0.0003	29.6 ± 14.8	44.6 ± 23.9	< 0.0001
Injections per day	3.0 ± 0.9	4.2 ± 1.5	< 0.0001	2.2 ± 0.6	3.0 ± 1.2	< 0.0001
Combination with sulphonylureas (%)	1.5	0	0.996	45.8	6.8	< 0.0001
Self-monitoring						
Blood glucose (*n*/week)	2.5 ± 6.2	21.1 ± 11.5	< 0.0001	1.0 ± 3.9	14.9 ± 10.7	< 0.0001
Urine glucose (*n*/week)	2.9 ± 5.6	0.8 ± 3.1	0.0002	2.1 ± 4.3	1.5 ± 3.9	0.376

[a] Mean normal HbA_{1c} in 1989/1990 4.15 % (SD 0.54); [b] in 1994/1995 5.1 % (SD 0.38)

chi-square test, Fisher's exact test for frequencies at or below 5 and Wilcoxon's rank sum test were used. Significance was defined at the 0.05 level.

Results

In 1994/1995 according to WHO criteria [18] 127 patients (52.0 %) suffered from IDDM and 117 patients (47.9 %) from NIDDM. Patients' treatment data and data on quality of diabetes care for the populations 1994/1995 compared to 1989/1990 are summarized in Table 2.

Quality of diabetes care. For the total group of IDDM patients examined, the HbA_{1c} (HbA_{1c}/mean normal) increased from 1989/1990 (1.52 ± 0.31) compared to 1994/1995 (1.65 ± 0.35, $p = 0.0018$). The HbA_{1c} of patients under specialized care in 1994/1995 was similar (1.54 ± 0.27, $n = 47$) to patients in 1989/1990 (1.52 ± 0.31, $n = 131$, $p = 0.0018$) and significantly better than that for patients treated by non-specialized physicians in 1994/1995 (1.71 ± 0.38, $n = 80$, $p = 0.0087$). In NIDDM the HbA_{1c} was similar in 1994/1995 (1.75 ± 0.4 HbA_{1c}/mean, $n = 117$) compared to 1989/1990 (1.78 ± 0.4, $n = 59$, $p = 0.67$). There were no differences between the groups as regards education, profession, unemployment or other socioeconomic factors.

There was a marked increase in the number of insulin injections and the frequency of self-monitoring in 1994/1995 compared to 1989/1990. Regular blood glucose self-monitoring (i.e. at least one test per week) was performed by 93 % of IDDM (22.7 ± 10.2 tests/week) and 87 % of NIDDM patients (17.2 ± 9.8 tests/week), in contrast to only 56 % of IDDM (4.5 ± 7.8 tests/week) and 24 % of NIDDM patients (4.4 ± 7.3 tests/week) in 1989/1990. The number of insulin injections per day increased significantly in

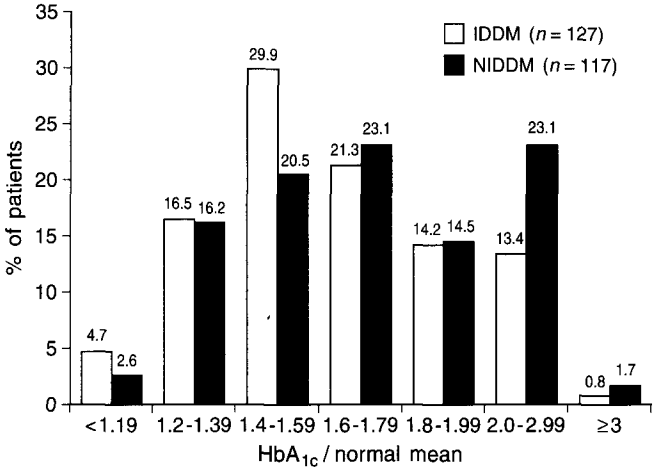

Fig. 1. Distribution of HbA_{1c} normal mean in IDDM and NIDDM patients in 1994/1995

IDDM and NIDDM patients. Eighty-five percent ($n = 108$) of IDDM and 48 % ($n = 56$) of NIDDM patients performed insulin therapy with short-acting and mixed/NPH-insulin with mostly 4 to 6 injections per day.

In IDDM patients there were no correlations between HbA_{1c} and age ($r = -0.04$, $p = 0.66$), diabetes duration ($r = 0.07$, $p = 0.47$), insulin dosage/kg body weight ($r = 0.18$, $p = 0.07$) or the number of insulin injections/day ($r = 0.09$, $p = 0.33$). But we found a positive correlation between systolic blood pressure and HbA_{1c} ($r = 0.2$, $p = 0.036$) and a negative correlation between HbA_{1c} and body mass index ($r = -0.26$, $p = 0.0062$) and HbA_{1c} and participation in a 5-DTTP for intensified conventional insulin therapy [22] ($r = -0.22$, $r = 0.023$).

Similar results were found for NIDDM patients: a negative correlation between HbA_{1c} and body mass index ($r = -0.34$, $p = 0.0065$) and HbA_{1c} and participation in a 5-DTTP for type 2 diabetic patients with

Table 3. Incidence of acute diabetes complications (severe hypoglycaemia: glucagon i.v., glucagon-injection, ketoacidosis with hospitalization) 1989/1990 versus 1994/1995

	IDDM			NIDDM		
	1989/1990	1994/1995	*p* value	1989/1990	1994/1995	*p* value
No. of patients (%)						
Severe hypoglycaemia						
Including pregnancy	10 (8%)	16 (12.6%)	0.264	1 (2%)	5 (4.3%)	0.653
Ketoacidosis	2 (1.6%)	2 (1.6%)	0.707	0	1 (0.9%)	0.726

Table 4. Diabetes late complications in patients examined 1989/1990 versus 1994/1995

	IDDM			NIDDM		
	1989/1990	1994/1995	*p* value	1989/1990	1994/1995	*p* value
No. of patients (%)	131	127		59	117	
Fundoscopy performed	131 (100%)	97 (76%)	< 0.001	59 (100%)	79 (68%)	< 0.001
Stage 1	25 (19%)	21 (22%)	0.726	5 (8%)	17 (22%)	0.066
Stage 2	16 (12%)	27 (28%)	0.008	7 (12%)	17 (22%)	0.210
Stage 3	5 (4%)	10 (10%)	0.166	2 (3%)	3 (3%)	0.739
Previous photo-/lasercoagulation	24 (18%)	37 (29%)	0.095	11 (19%)	15 (13%)	0.335
Neuropathy[a]		30 (24%)			44 (38%)	
Impaired vibration perception[b]	33 (25%)	25 (20%)	0.498	16 (27%)	20 (17%)	0.124
Tuning fork score ≤ 4[c]	18 (14%)	21 (17%)	0.696	21 (35%)	24 (21%)	0.041
Foot problems						
Foot ulcers	3 (2%)	3 (2%)	0.708	1 (2%)	6 (5%)	0.489
Amputation	2 (2%)	4 (3%)	0.652	2 (3%)	5 (4%)	0.9
Nephropathy						
Serum creatinine ≥ 177 µmol/l	2 (2%)	5 (4%)	0.419	0	1 (1%)	0.726
Albuminuria investigated in *n* (%) of patients	114 (87%)	119 (94%)	0.109	45 (76%)	107 (91%)	0.011
Albumin > 20 $\leq$ 200 mg/l	26 (23%)	18 (15%)	0.201	15 (33%)	29 (27%)	0.440
Albumin > 200 mg/l	6 (5%)	7 (6%)	1.0	6 (13%)	9 (8%)	0.356

[a] According to Young et al. [4], [b] abnormal age-related score according to Liniger et al. [30]; mean at both sides, [c] on at least one side

insulin therapy [23] and between the frequency of blood glucose monitoring ($r = -0.28, p = 0.03$).

Acute diabetic complications. The incidence of acute complications, severe hypoglycaemia and ketoacidosis, remained stable in 1989/1990 compared to 1994/1995 as shown in Table 3.

Retinopathy. In 1994/1995 funduscopy was performed in 76% of IDDM and in 68% of NIDDM patients. The prevalence of retinopathy increased in IDDM and NIDDM (Table 4). Blindness (visus < 0.02) was found in three patients in 1994/1995 (IDDM $n = 1$, NIDDM $n = 2$), whereas there was one blind patient identified in 1989/1990.

Neuropathy. According to the neuropathy disability and symptom score used for diagnosis of peripheral neuropathy [4] in 1994/1995 peripheral neuropathy was found in 24% of IDDM and 38% of NIDDM patients. The prevalence of impaired vibration perception (age-related score according to Liniger et al. [31] at the first metatarsal bone) remained unchanged (Table 4).

Nephropathy. There was no significant change in the prevalence of nephropathy, either in albuminuria or in serum creatinine (Table 4). In IDDM patients early renal failure was found in four patients after a mean duration of diabetes of 26.3 ± 11.2 (range 8–37) years. Two patients had received a renal transplant.

In IDDM patients a positive correlation was found between albuminuria and duration of diabetes ($r = 0.3$, $p = 0.0015$) and serum creatinine ($r = 0.55$, $p < 0.001$) and between systolic blood pressure and albuminuria ($r = 0.19$, $p = 0.04$). In NIDDM patients there was a positive correlation between albuminuria and serum creatinine ($r = 0.26$, $p = 0.04$), but there were no correlations between age and duration of diabetes or blood pressure.

Smoking. The number of current smokers in IDDM patients decreased significantly from 43% in 1989/1990 to 32% in 1994/1995 ($p = 0.0005$) and in NIDDM from 32% to 24% ($p < 0.00001$).

Multivariate analysis. Performing multivariate analysis for IDDM patients, the most important factor

associated with HbA_{1c} (R squared 0.053) was regular treatment by a diabetologist ($c = -0.17$, $p = 0.009$). All other parameters, investigated in the model (sex, age and duration of diabetes, BMI, frequency of insulin injections/day, frequency of self-monitoring, insulin dosage and educational level) had no statistically significant associations with HbA_{1c}.

The most important parameters associated with HbA_{1c} in NIDDM patients (R squared 0.15) were the frequency of blood glucose self-tests/week ($c = -0.013$, $p = 0.003$) and the daily insulin dosage ($c = 0.48$, $p = 0.01$). No associations were found for age, BMI, treatment by specialized physicians, diabetes duration, frequency of insulin injections, urine glucose self tests/week and educational level.

Discussion

Both IDDM and NIDDM are common diseases associated with reduced life expectancy and high mortality and morbidity [1, 2, 32, 33]. The most important factors for preventing late complications are better quality of diabetes care with near normoglycaemia, and regular screening of patients [6, 7, 10]. However, to evaluate the efficacy of centralized diabetes care in 1989/1990 we chose a selection-free population of insulin-treated diabetic patients aged 16 to 60 years. Older patients were not studied because diabetes is only one facet of their multimorbidity. In these patients HbA_{1c} is not the primary parameter to estimate care quality. For these patients individualized treatment goals are crucially important. Younger patients are mostly in employment and the goal of the therapy is near normoglycaemia to prevent late complications [34].

In 1989/1990 under a centralized diabetes care system [14, 15, 35, 36] all diabetic patients were registered and regularly examined at regional diabetes care centres. Looking at HbA_{1c} in insulin-treated IDDM and NIDDM patients aged 16 to 60 years, quality of diabetes care appeared to have been successfully achieved. Regional diabetes care centres existed overall in the former GDR and everywhere patients were treated following the same guidelines. Although results from other East European countries showed very high HbA_{1c} levels before intervention [37] quality of diabetes care in Jena seems to be representative of the whole GDR [36]. But in 1994/1995, at the time this follow-up trial was performed, this centralized diabetes care system no longer existed. Most patients are now treated by GPs, and about 19 % by diabetologists [16]. Up to the present no data derived from non-selected populations have been available to measure influences of the shift from centralized to private health care systems. Based on the rationale that an accurate estimation of the diabetes prevalence can be assessed only by using more than one source for identification of diabetic patients [38, 39], in the present trial three independent sources were used to prevent a bias due to patient selection.

In IDDM patients under specialized care the HbA_{1c} was similar compared to the population studied in 1989/1990. But it was higher for IDDM patients treated by non-specialized physicians only. There was no positive selection of patients under specialized care regarding socioeconomic factors and the prevalence of late complications. In the multivariate analysis we found only one parameter independently associated with HbA_{1c}: care by a diabetologist.

In NIDDM patients we found no significant difference in HbA_{1c} in patients under specialized or non-specialized care. But, more than half of general practitioners and physicians for internal medicine [16] took part in postgraduate training courses for NIDDM patients [40]. This may be one of the reasons for the stability of treatment quality in NIDDM patients. There was an impressive increase in regular blood glucose self-monitoring from 1989/1990 to 1994/1995 in IDDM (from 56 to 93 %) and in NIDDM (from 24 to 87 %). However, in the multivariate analysis the frequency of blood glucose monitoring was the most independent factor associated with HbA_{1c} in insulin-treated NIDDM patients only. Perhaps this is a further reason why impairment of HbA_{1c} was prevented in NIDDM patients, whereas in older NIDDM patients no benefit of blood glucose self-monitoring has been reported [41]. Another issue concerns the question of whether insulin monotherapy is really superior to combination therapy with insulin and oral antidiabetic drugs. Regarding the disappearance of deterioration of HbA_{1c} after withdrawal of most of the sulfonylureas in the NIDDM population studied, this issue might be negotiated. In the UKPDS [8, 9], up to now no advantages of therapies with oral antidiabetic drugs have been seen. In numerous trials the efficacy of DTTP [22, 23, 29] for both IDDM and NIDDM patients, with or without insulin treatment, has been established. The quality of diabetes care improved, the incidence of acute complications and frequency and duration of patients' hospitalization could be reduced or were stable [24–27, 42–45]. Following these results, training and teaching in diabetes management and care for people of all ages with both IDDM and NIDDM and for their families was one of the central recommendations of the St. Vincent Declaration action programme, and also of other national and international guidelines for treatment of diabetic subjects [18, 28, 46–49].

Although in several trials for selected patients, educated at our centre, significant improvement of quality of diabetes care after participation in 5-DTTP was established [26, 27, 50–52] no significant improvement in quality of diabetes care in the selection-free population of diabetic patients could be

found. On the other hand, after the discontinuation of the centralized health care system, an impairment in quality of diabetes care was shown in IDDM patients without specialized care, but there was no increase in the incidence of ketoacidoses as was expected [53]. Together with the disappearance of the centralized diabetes care system there were great changes in individual lifestyles which may interact with patients' quality of diabetes care: for example need for more flexibility, the availability of different foods, new opportunities to travel and a higher unemployment rate.

The prevalence of neuropathy and microalbuminuria were similar to 1989/1990 and have been reported by other groups [3–5, 54–59]. Fortunately the number of smokers decreased in our study, despite a tremendous increase in cigarette advertisements. Perhaps the lower frequency of smokers in 1994/1995 versus 1989/1990 in IDDM and NIDDM led to a reduction of overt nephropathy. Numerous trials clearly demonstrated that cigarette smoking appears to be a strong risk factor for the development and progression of nephropathy in diabetic patients [60, 61].

However, regarding retinopathy there was a significant increase in frequency in 1994/1995 compared to 1989/1990 in both IDDM and NIDDM, including a bias resulting from missing up to a quarter of eye examinations in 1994/1995. Concerning this tendency and the increase of HbA_{1c} in IDDM patients without specialized care, modifications of the present private health care system are mandatory to prevent inconvenient and costly treatment of diabetes complications in the future.

In particular regarding the changes in health care systems in other Eastern European countries, the results of the present non-selected, population-based trial are important. Models like the St. Vincent Declaration action programme or the WHO Partnerships for Health, aiming at the improvement of long-term outcome of patients and helping them to improve self-management, should be emphasized, but must be also critically monitored and evaluated. In all in- and outpatient centres for diabetes care it must be mandatory to take part in a regular system of quality assurance [62, 63] as shown by the Working Group of structured diabetes therapy of the German Diabetes Association [45]. However, only a prospective controlled trial could fully answer the question of whether IDDM patients who continue to look for specialized care will have a better outcome.

References

1. Panzram G, Zabel-Langhennig R (1981) Prognosis of diabetes mellitus in a geographically defined population. Diabetologia 20: 587–591
2. Panzram G (1987) Mortality and survival in type 2 (non-insulin-dependent) diabetes mellitus. Diabetologia 30: 123–131
3. Ratzmann KP, Gorr K, Schneider H (1994) Prävalenz diabetesbedingter Erblindungen. Eine Populationsstudie an 70203 Diabetikern. Diab Stoffw 3: 261–264
4. Young MJ, Boulton AJM, Macleod AF, Williams DRR, Sonksen PH (1993) A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. Diabetologia 36: 150–154
5. The United States Renal Data System. USRDS 1994 Annual Data Report (1994) The National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. MD
6. The Diabetes Control and Complications Trial Research Group (1993) The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 329: 977–986
7. Reichard P, Nilsson BY, Rosenqvist U (1993) The effect of long-term intensified insulin treatment on the development of microvascular complications of diabetes mellitus. N Engl J Med 329: 304–309
8. UK Prospective Diabetes Study Group (1995) U.K. prospective diabetes study 16. Overview of 6 years' therapy of type II diabetes: a progressive disease. Diabetes 44: 1249–1258
9. Turner R, Cull C, Holman R for the United Kingdom Prospective Diabetes Study Group (1996) United Kingdom Prospective Diabetes Study 17: A 9-year update of a randomized, controlled trial on the effect of improved metabolic control on complications in non-insulin-dependent diabetes mellitus. Ann Intern Med 124: 136–145
10. Ohkubo Y, Kishikawa H, Araki E et al. (1995) Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. Diab Res Clin Pract 28: 103–117
11. Gries FA, Piwernetz K (eds) (1994) St. Vincent Register 1994. Beiträge zur Umsetzung der St.-Vincent-Deklaration in Deutschland. Verlag Kirchheim, Mainz, Germany
12. King H, Gruber W, Lander T (eds) (1995) Report of a WHO meeting. Implementing national diabetes programmes. WHO Division of Noncommunicable Diseases. Geneva
13. St. Vincent Group (1990) Diabetes care and research in Europe. The St. Vincent Declaration. Diabet Med 7: 360
14. Müller UA, Ross IS, Klinger H, Geisenheimer S, Chantelau EA (1993) Quality of centralized diabetes care: a population-based study in the German Democratic Republic 1989–1990. Acta Diabetol 30: 166–172
15. Schulz B, Bibergeil H, Rybka J, Koev D (1988) Strategy and structure of diabetes health care in some European Socialist countries. In: Krall LP (ed) World book of diabetes in practice. Elsevier, Amsterdam 3: 375–376
16. Müller UA, Müller R, Meier F (1995) Inzidenz von Ketoazidosen bei Diabetes mellitus unter zentralisierter und dezentralisierter Diabetesbetreuung in Thüringen. Diab Stoffw 4: 71–76
17. Jackson JL (1997) The German health system. Lessons for reform in the United States. Arch Int Med 157: 155–160
18. World Health Organization (1985) Diabetes mellitus. Technical reports series 727. WHO, Geneva
19. Bruns W (1989) Behandlung mit Diät. In: Bibergeil H (ed) Diabetes mellitus. VEB Gustav Fischer Verlag, Jena, pp 254–315

20. Mehnert H (1994) Ernährungstherapie. In: Mehnert H, Schöffling K, Standl E, Usadel KH (eds) Diabetologie in Klinik und Praxis. Georg Thieme Verlag Stuttgart, pp 162–210
21. Chantelau E (1995) Diät (?) bei Diabetes mellitus. In: Berger M (ed) Diabetes mellitus. Urban und Schwarzenberg Verlag, Munich, pp 126–158
22. Scholz V, Grüßer M, Bott U, Jörgens V (1997) Behandlungs- und Schulungsprogramm für Typ-I-Diabetiker. Verlag Kirchheim, Mainz
23. Berger M, Bott U, Grüßer M et al. (1990) Behandlungs- und Schulungsprogramm für Typ-II-Diabetiker, die Insulin spritzen. Deutscher Ärzte-Verlag, Cologne
24. Mühlhauser I, Jörgens V, Berger M (1983) Bicentric evaluation of a teaching programme for type I diabetic patients. Diabetologia 25: 470–476
25. Mühlhauser I, Bruckner I, Berger M et al. (1987) Evaluation of an intensified insulin treatment and teaching programme as routine management of type 1 (insulin-dependent) diabetes. The Bucharest-Düsseldorf Study. Diabetologia 30: 681–690
26. Müller UA, Hunger-Dathe W, Kobes M, Reuber E, Kirchner D (1995) Qualität der Stoffwechseleinstellung bei Typ-I-Diabetikern ein Jahr nach Teilnahme an einem strukturierten Behandlungsprogramm für intensivierte konventionelle Insulintherapie. Diab Stoffw 4: 9–13
27. Schiel R, Müller UA, Kalbas B, Franke I (1996) Diabeteswissen und Lebensqualität zweier Patientengruppen mit intensivierter konventioneller Insulintherapie. Vier Jahre bzw. unmittelbar nach Teilnahme an einem strukturierten 5-Tage-Behandlungsprogramm. Diab Stoffw 5: 63–68
28. Assal JP, Mühlhauser I, Pernet A, Gfeller R, Jörgens V, Berger M (1985) Patient education as the basis for diabetes care in clinical practice and research. Diabetologia 28: 602–613
29. Berger M, Grüßer M, Jörgens V et al. (1987) Diabetesbehandlung in der Praxis: Behandlungs- und Schulungsprogramm für Typ-II-Diabetiker, die nicht Insulin spritzen. Deutscher Ärzte-Verlag, Cologne
30. Kohner E, Porta M (1992) Screening for diabetic retinopathy in Europe: a field guide book. WHO Regional Office for Europe, Kopenhagen
31. Liniger C, Albeanu A, Bloise D, Assal JPh (1990) The tuning fork revisited. Diabet Med 7: 859–864
32. Walters DP, Gatling W, Houston AC, Mullee MA, Julious SA, Hill RD (1994) Mortality in diabetic subjects: An eleven-year follow-up of a community-based population. Diabet Med 11: 968–973
33. Muggeo M, Verlato G, Bonora E et al. (1995) The Verona diabetes study: a population-based survey on known diabetes mellitus prevalence and 5-year all-cause mortality. Diabetologia 38: 318–325
34. Berger M, Jörgens V, Flatten G (1996) Health care for persons with non-insulin-dependent diabetes mellitus. The German experience. Ann Intern Med 124: 153–155
35. Ratzmann KP (1991) Eine Analyse von alters- und geschlechts-spezifischer Diabetesprävalenz sowie Behandlungsart: Die Berlin-Studie. Akt Endokrin Stoffw 12: 220–223
36. Bibergeil H (1989) Diabetiker-Dispensairebetreuung. In: Biberbeil H (ed) Diabetes mellitus. VEB Gustav Fischer Verlag Jena, pp 669–673
37. Starostina EG, Antsiferov M, Galstyan GR et al. (1994) Effectiveness and cost-benefit analysis of intensive treatment and teaching programmes for type 1 (insulin-dependent) diabetes mellitus in Moscow – blood glucose versus urine glucose self-monitoring. Diabetologia 32: 170–176
38. Vaccaro O, Imperatore G, Ferrara A, Palombino R, Riccardi G (1992) Epidemiology of diabetes mellitus in Southern Italy: a case-finding method based on drug prescription. J Clin Epidemiol 45: 835–839
39. Bruno G, Bargero G, Vuolo A, Pisu E, Pagano G (1992) A population-based prevalence survey of known diabetes mellitus in northern Italy based upon multiple independent sources of ascertainment. Diabetologia 35: 851–856
40. Grüßer M, Jörgens V (1992) Diabetes in der Praxis. Fortbildungsveranstaltung „Diabetes mellitus" für Kassenärzte. Projekt des Bundesministeriums für Gesundheit und des Zentralinstitutes für kassenärztliche Versorgung in der Bundesrepublik Deutschland in Zusammenarbeit mit der Deutschen Diabetesgesellschaft e. V., der Kassenärztlichen Bundesvereinigung und den Kassenärztlichen Vereinigungen der Länder. Deutscher Ärzteverlag Köln
41. Müller UA, Janz H, Rauchfuß J et al. (1994) Behandlungsqualität von Typ-II-Diabetikern 2 Jahre nach Umstellung auf Insulin und Teilnahme an einem strukturierten Schulungsprogramm im Vergleich zu herkömmlicher Instruktion im Krankenhaus. Diab Stoffw 3: 116 (Abstract)
42. Kronsbein P, Mühlhauser I, Venhaus A, Jörgens V, Scholz V, Berger M (1988) Evaluation of a structured treatment and teaching programme on non-insulin-dependent diabetes. Lancet 1407–1411
43. Jörgens V, Grüßer M, Bott U, Mühlhauser I, Berger M (1993) Effective and safe translation of intensified insulin therapy to general internal medicine departments. Diabetologia 36: 99–105
44. Pieber TR, Holler A, Siebenhofer A et al. (1995) Evaluation of a structured teaching and treatment programme for type 2 diabetes in general practice in a rural area of Austria. Diabet Med 12: 349–354
45. Müller UA, Reinauer KM, Voss M and German Working Group for structured diabetes care (ASD) of the German Diabetes Association (1996) Continuous quality management of structured treatment and teaching programmes for type 1 diabetes on the national level in Germany. Diabetologia 39: A29 (Abstract)
46. Krans HMJ, Porta M, Keen H, Staehr Johansen K (eds) (1995) Diabetes care and research in Europe: the St. Vincent Declaration action programme. Implementation document. G Ital Diab 15: 1–84
47. Alberti KGMM, Gries FA (1988) Management of non-insulin-dependent diabetes mellitus in Europe: A consensus view. Diabet Med 5: 275–281
48. Alberti KGMM, Gries FA, Jervell J, Krans HMJ for the European NIDDM Policy Group (1994) A desktop guide for the management of non-insulin-dependent diabetes mellitus (NIDDM): An update. Diabet Med 11: 899–909
49. Berger M, Mühlhauser I (1995) Implementation of intensified insulin therapy: a European perspective. Diabet Med 12: 201–208
50. Müller UA, Janz H, Rauchfuß J et al. (1994) Behandlungsqualität von Typ-II-Diabetikern 2 Jahre nach Umstellung auf Insulin und Teilnahme an einem strukturierten Schulungsprogramm im Vergleich zu herkömmlicher Instruktion im Krankenhaus. Diab Stoffw 3: 116 (Abstract)
51. Müller UA, Mertes B, Hunger-Dathe W et al. (1994) Intensivierte Insulintherapie bei jüngeren Typ-II-Diabetikern-Behandlungsqualität 1 Jahr nach Teilnahme an einem strukturierten 5-Tage-Behandlungs- und Schulungsprogramm. Diab Stoffw 3: 170 (Abstract)
52. Schiel R, Müller UA, Ulbrich S (1997) Long-term efficacy of a 5-day structured teaching and treatment programme for intensified conventional insulin therapy and risk for severe hypoglycemia. Diab Res Clin Pract 35: 41–48

53. Editorial (1992) Unsicherheit zum Jahresende. Diabetes Journal 41: 2
54. Mühlhauser I, Sulzer M, Berger M (1992) Quality assessment of diabetes care according to the recommendations of the St. Vincent Declaration: a population-based study in a rural area of Austria. Diabetologia 35: 429–435
55. Walters DP, Gatling W, Mullee MA, Hill RD (1992) The prevalence of diabetic distal sensory neuropathy in an English community. Diabet Med 9: 349–353
56. Ziegler D, Gries FA (1992) Epidemiologie der peripheren diabetischen Neuropathie. Diab Stoffw 2: 24–28
57. Amthor KF, Dahl-Jörgensen K, Berg TJ et al. (1994) The effect of 8 years strict glycemic control on peripheral nerve function in IDDM patients: the Oslo study. Diabetologia 37: 579–584
58. Andersen AR, Christiansen JS, Andersen JK, Kreiner S, Deckert T (1983) Diabetic nephropathy in type 1 (insulin dependent) diabetes: an epidemiological study. Diabetologia 25: 496–501
59. Ballard DJ, Humphrey LL, Melton LJ et al. (1988) Epidemiology of persistent proteinuria in type II diabetes mellitus: population-based study in Rochester, Minnesota. Diabetes 37: 405–412
60. Mühlhauser I, Sawicki P, Berger M (1986) Cigarette smoking as a risk factor for macroproteinuria and proliferative retinopathy in type 1 (insulin-dependent) diabetes. Diabetologia 29: 500–502
61. Couper JJ, Staples AJ, Cocciolone R, Nairn J, Badcock N, Henning P (1994) Relationship of smoking in children with insulin-dependent diabetes. Diabet Med 11: 666–669
62. Mühlhauser I (1995) Effizienznachweis und Qualitätskontrolle. In: Berger M (ed) Diabetes mellitus. Urban und Schwarzenberg Verlag, Munich, pp309–316
63. Brook RH, McGlynn EA, Cleary PD (1996) Measuring quality of care. (Quality of health care, Part 2). N Engl J Med 335: 966–970