

Targets and Reality: A Comparison of Health Care Indicators in the U.S. (Pittsburgh Epidemiology of Diabetes Complications Study) and Hungary (DiabCare Hungary)

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OBJECTIVE — In the U.S., both primary care and specialist physicians share in the care of type 1 diabetic patients, often in an informal collaboration. In Hungary, however, type 1 diabetic patients are generally managed in special centralized diabetes units. These different treatment settings may lead to different health care practices and outcomes. To determine if this is true, diabetes care indicators and complications were compared across representative study populations from the 2 countries.

RESEARCH DESIGN AND METHODS — The Pittsburgh Epidemiology of Diabetes Complications Study (EDC) is a prospective cohort of childhood-onset type 1 diabetic patients. DiabCare Hungary, a multicenter cross-sectional study, was developed for quality control purposes and provides a nationwide data set of diabetic patients. We identified 2 comparable populations (EDC, $n = 416$; DiabCare, $n = 405$) in terms of age (≥ 14 years) and age at onset (< 17 years).

RESULTS — EDC patients were less likely to receive diabetes education ($P < 0.0001$), see an ophthalmologist ($P < 0.0001$), be treated by diabetologists ($P < 0.0001$), or perform self-monitoring of blood glucose ($P < 0.0001$). They were more likely to use conservative insulin regimens (i.e., 1–2 injections/day, $P < 0.0001$) and have a higher glycated hemoglobin ($P < 0.0001$). DiabCare patients more often experienced severe hypoglycemia ($P < 0.01$) and had a lower prevalence of proliferative retinopathy ($P < 0.0001$), legal blindness ($P < 0.05$), and albuminuria (≥ 30 mg/day, $P < 0.01$). No significant differences in macrovascular complications were seen, although rates were generally low.

CONCLUSIONS — These data suggest that the 2 populations differ by their diabetes care practices, degree of glycemic control, and microvascular complication status.

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Abbreviations: ASD, German Diabetes Association; CHP, Children's Hospital of Pittsburgh; DCCT, Diabetes Control and Complications Trial; EDC, Epidemiology of Diabetes Complications Study; HPLC, high-performance liquid chromatography; ISG, Italian Study Group of the St. Vincent Declaration; JEVIN, Jena's St. Vincent Trial.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

The enormous cost of health care in the U.S. has led to the widespread use of managed care. Depending on the definition used, up to 95% of employee health care benefits in 1990 fell under some form of managed care (1). Most office visits for diabetes (76–90%) were made to primary care physicians, whereas visits to diabetologists and endocrinologists (7.9%) were rare (2,3).

In contrast, treatment of diabetic patients in Hungary is centralized, although in recent years, type 2 diabetic patients without specific problems have been referred back to general practitioners. All type 1 diabetic patients continue to be treated in specialized diabetes care centers (4). To facilitate the goal to treat all type 1 diabetic patients in specialized care centers, the Ministry of Health has made free insulin available only to patients who attend such specialty centers at least semi-annually.

The effects of different health care structures on process and outcome indicators are controversial. Jena's St. Vincent Trial (JEVIN) Study from the former German Democratic Republic (East Germany) reported a significant worsening of glycemic control among type 1 diabetic patients after the decentralization of the health care system (5). In other European countries, intensive insulin therapy was successfully implemented in primary care after extensive inpatient education (6–8), and in the U.S., several initiatives with local quality-control procedures have shown significant beneficial effects on diabetes care (3,9).

Because of the differences in the health care structures of the 2 countries and the controversy concerning centralized care, we compared the care characteristics and prevalence of macrovascular and microvascular complications in representative samples of type 1 diabetic patients from the U.S. (Pittsburgh Epidemiology of Diabetes Complications Study [EDC]) and from Hungary (DiabCare Hungary).

RESEARCH DESIGN AND

METHODS — The EDC is a prospective cohort study of type 1 diabetic patients who were all diagnosed before 17 years of age between 1950 and 1980 and seen within 1 year of diagnosis at the Children's Hospital of Pittsburgh (CHP). The CHP registry has been shown to have similar epidemiologic characteristics to the population-based Allegheny County Registry, with 70% overlap (10). Baseline examination was between 1986 and 1988, after which the 658 subjects were followed biennially.

The World Health Organization–International Diabetes Federation joint project, called DiabCare, uses a standardized data set that was developed for quality control purposes (11,12) and was widely implemented after a 1993 pilot study (13,14). In Hungary, diabetes care providers from different regions sent data representing >4,000 treated patients to the evaluating center. These data represented 11 of the 20 counties and 18 of the 88 regional diabetes care centers in Hungary.

For the current cross-sectional analysis, only patients aged >14 years with onset before age 17 years, who had a visit (in either study) between 1 January 1994 and 31 December 1997 (DiabCare, $n = 405$; EDC, $n = 416$) were included. If multiple visits occurred, data from the first visit were used. The Hungarian cohort is ~22% of the estimated total type 1 childhood diabetic population, which is consistent with the 20% response rate of care centers (15).

The EDC has been described in detail elsewhere (16,17). Briefly, participants were sent questionnaires 2–4 weeks before their scheduled visit. These questionnaires contained items that elicited demographic, health care, and medical history information. Physician specialty was determined as previously described (18). Receiving specialist care was defined as care from a board-certified endocrinologist, a physician with a self-declared interest in diabetes, or attendance at a diabetes clinic (18). EDC clinical evaluation included blood and urine samples, physician examination, electrocardiogram, and 3-field stereo fundus photography.

In DiabCare, the treating physician annually records clinical data based on the last entry for that year. Physician specialty was based on obtaining the Hungarian Diabetes Association's diabetologist certification.

Glycated hemoglobin values were determined by high-performance liquid

chromatography (HPLC) in the EDC (Diamat; Bio-Rad, Hercules, CA), whereas different HPLC and affinity methods were used in the Hungarian centers. The HbA_{1c} levels from the 2 data sets were compared using the following 2 different methods to calculate a relative HbA_{1c}:

1. The Working Group on Structured Diabetes Therapy of the German Diabetes Association (ASD): relative HbA_{1c} = HbA_{1c}/mean HbA_{1c} of the normal control group (8); and
2. The Italian Study Group of the St. Vincent Declaration (ISG): relative HbA_{1c} = HbA_{1c}/upper limit of laboratory normal range (19).

Frequency of blood glucose self-monitoring in EDC was determined by the patient's response to "testing blood for glucose at least weekly in the last year." In DiabCare, the treating physician calculated the average number of blood glucose tests from the patient's diary. Similarly, intensive insulin treatment was defined as >2 insulin injections/day, based on questionnaire data in the EDC and the physician's prescription (confirmed by the patient's diary) in DiabCare.

Severe hypoglycemic emergency during the last year was defined as hypoglycemia resulting in "unconsciousness and/or medical treatment" in EDC, and in DiabCare as "requiring professional help and treatment with intravenous glucose or glucagon injection."

Diabetes education during the last year was defined in both studies based on questionnaire response (outpatient in EDC; inpatient or outpatient in DiabCare). Retinopathy was determined by stereo fundus photographs that were graded using the modified Arlie House System in EDC (20) and by a dilated eye examination performed by a trained ophthalmologist in DiabCare.

In the EDC, proliferative retinopathy was indicated by grade 60+; in the DiabCare studies, it was indicated by new vessels on the optic disk or elsewhere on the retina, preretinal or vitreous hemorrhage, fibrous tissue, or a history of laser treatment. The definition of legal blindness (a best-corrected visual acuity for the better eye of $\leq 6/60$) was identical in both cohorts.

The 24-h urinary albumin excretion rate was determined in a central laboratory using immunonephelometry in EDC (Ektachem 400 analyzer; Eastman Kodak, Rochester, NY) and in local laboratories in

DiabCare, with albuminuria defined as ≥ 30 mg/day.

Hypertension was defined as blood pressure $\geq 140/90$ mmHg or use of antihypertensive medication in both studies. Blood pressure was measured using a random zero sphygmomanometer (Hawksley, U.K.) in EDC and by mercury or aneroid sphygmomanometer in DiabCare. Angina was diagnosed by the examining physician in both studies, and a history of stroke or myocardial infarction was confirmed with hospital records in both studies.

Statistical analysis

Odds ratios (EDC vs. DiabCare) were calculated by multiple logistic regression adjusting for age, duration of diabetes, and sex, whereas glycemic control was similarly compared using multiple linear regression. Log transformation of relative glycated hemoglobin improved the normality of its distribution. A subgroup analysis was also performed comparing EDC patients treated in specialty care ($n = 203$) with the DiabCare patients.

RESULTS — DiabCare patients were significantly younger (29.2 ± 9.6 vs. 35.0 ± 8.2 years, $P < 0.0001$), had a shorter duration of diabetes (18.8 ± 10.5 vs. 26.6 ± 7.8 years, $P < 0.0001$) and, after adjustment for age, sex, and duration of diabetes, had a lower BMI (22.8 ± 2.7 vs. 25.0 ± 3.9 kg/m², $P < 0.0001$).

Figure 1 shows the health care characteristics of the populations. Of the DiabCare patients, 92% were treated by a specialist compared with only 56% of the EDC patients. Almost all DiabCare subjects, but somewhat fewer EDC patients, performed self-monitoring of blood glucose at least weekly. Significantly more DiabCare patients received diabetes education during the last year. The vast majority of Hungarian type 1 diabetic patients were on an intensive insulin regimen, whereas most EDC patients were on a conservative (≤ 2 injections daily) insulin regimen. Ophthalmological checkups in the last year were done more often among the Hungarian subjects.

Hypoglycemic emergencies were more frequently recorded in the DiabCare database; however, all-cause hospitalization was similar. Limiting the EDC population to patients seeing a specialist reduced the magnitude of the EDC–DiabCare differences, although they all remained significant, except for hypoglycemia. Glycated

Health Care characteristics				Odds ratio and 95% confidence interval			
	EDC	EDC Specialty	DiabCare	0.1	1	10	100
Treated by diabetologist	56.3*	100.0	92.3				
Self-monitoring of blood glucose	78.3*	87.3*	97.8				
Diabetes education	17.2*	22.6*	53.7				
Intensive insulin regimens	28.9*	40.7*	88.4				
Ophthalmological visit	70.9*	77.0*	92.2				
Hypoglycemic emergencies	3.4†	4.3	8.3				
All cause hospitalization	21.2	25.0	26.4				
Relative HbA1(c) - ISG‡	1.44 ± 0.25*	1.41 ± 0.25*	1.31 ± 0.31				
Relative HbA1(c) - ASD‡	1.77 ± 0.32*	1.74 ± 0.33*	1.60 ± 0.39				
Microvascular complications							
Proliferative retinopathy	35.1*	33.7†	20.1				
Cataract	11.9*	14.6	3.5				
Legal blindness	4.3§	4.5§	1.9				
Albuminuria (≥30 mg/day)	46.4†	28.2	35.2				
End-stage renal failure	1.8	2.0	0.4				
Macrovascular complications							
Hypertension	19.4*	25.4§	34.6				
Stroke	0.2	0.1	0.1				
Angina	1.7	1.5	1				
Myocardial infarction	0.4	0.5	0.5				
Absent peripheral pulse	6.8	4.9	4.2				
Claudication	2.2	2.8	1.4				
Amputation above ankle	2.8	1.9	1.6				

Figure 1—Health care characteristics and prevalence of microvascular and macrovascular complications (%) and odds ratios (EDC vs. DiabCare) after adjustment for age, sex, and diabetes duration. * $P < 0.001$ vs. DiabCare; † $P < 0.01$ vs. DiabCare; ‡relative glycated hemoglobin (means ± SD) according to the ISG and the Working Group on Structured Diabetes Management of the ASD (see details in text); § $P < 0.05$ vs. DiabCare.

hemoglobin was significantly lower in the DiabCare population using either the ASD or ISG comparison method.

The prevalence of microvascular diabetic complications is shown in Fig. 1. Proliferative retinopathy, cataract, legal blindness, albuminuria, end-stage renal disease, and symptomatic neuropathy were all significantly more common in the EDC population. The EDC specialty sub-

group had results that were similar to those of the overall EDC group, except for a lower prevalence of albuminuria, which was similar to the results found in the DiabCare group.

There were no significant differences in the prevalence of macrovascular complications. Hypertension was significantly more frequent in the DiabCare population, and although the EDC specialty sub-

group had a higher prevalence (similar to that of the DiabCare patients), the difference remained significant.

Because older age and longer disease duration may cause less recent diabetes education and poorer short-term outcomes, a pair-matched analysis (on age, sex, and diabetes duration; $n = 169$) was also done. The results showed similarly higher frequency of preventive practices

(self-monitoring, ophthalmological checkups, intensive treatment, and diabetes education) among DiabCare patients, who also had lower calculated glycated hemoglobin and a lower frequency of microvascular complications (retinopathy and cataract).

CONCLUSIONS — In this study, we compared 2 cohorts of childhood-onset type 1 diabetic patients from 2 different countries with different health care structures. In Hungary, where the patients received centralized, specialized diabetes care, type 1 diabetic patients had a lower calculated glycated hemoglobin level and were more likely to be treated by a specialist, perform blood glucose self-monitoring, receive intensive insulin treatment, and suffer hypoglycemic emergencies. Hospitalization rates, however, were similar to those of EDC patients. The Hungarian cohort was also less likely to have reported microvascular complications (retinopathy, cataract, blindness, albuminuria, and end-stage renal failure) but more likely to be hypertensive. There were no significant differences in the prevalence of macrovascular complications.

A potential weakness of this study is the representativeness of the Hungarian cohort. It could be argued that the 20% of the centers that participated in the study had better care practices than nonparticipating centers. Some nonparticipating centers reported to DiabCare that they already collect similar data and did not want to duplicate the effort, whereas other centers complained of the lack of sufficient time to fill in the forms. We could identify no systematic biases characterizing the participating centers, which represent all geographic areas of Hungary. It should also be noted that the representation of national and regional centers was similar (~20%). Lastly, the representation of diabetologists as providers was similarly >90% among the nonparticipating centers, according to data from the Hungarian Diabetes Association. Although the inclusion of a national center for diabetic pregnancies significantly affected the sex distribution (which was controlled for during data analysis), the prevalence of concurrent pregnancies did not differ significantly (EDC 10%; DiabCare 9.2%).

The use of different data collection methodologies in the 2 studies is another potential source of bias. EDC patients provided questionnaire responses and were examined by trained examiners, regardless of their source of care. In the DiabCare

Study, however, the treating physician entered patient data, which might introduce ascertainment bias and may lead to systematic differences in recording certain practices, such as education. This is unlikely to have a major effect on many key variables, such as the frequency of self-monitoring (derived from the patients' diaries), the type of insulin regimen, or the frequency of ophthalmological examinations.

To determine if the differences noted were largely related to receiving specialist care, the health care characteristics of the specialist-treated EDC patients were compared with those of the DiabCare population. This analysis suggests that some discrepancies are explained, but major differences (e.g., frequency of intensive treatment and self-monitoring) remain. Another aspect of the health care system might also play a role in these findings: diabetes care centers in Hungary are hospital based, so it is more likely that patients visiting these clinics have better access to supporting professionals (e.g., ophthalmologists). We also suspect that DiabCare patients may be more compliant, since the doctor-patient relationship seems to be more paternalistic in Hungary (and Europe) than in the U.S. Thus, centralized care itself (including easy accessibility of pen devices, free insulin, and affordable self-monitoring supplies) is likely to have had a major effect.

Zgibor et al. (18) recently found in EDC that specialist care was associated with better glycemic control. There was no significant difference, however, in the frequency of complications, which suggests that the referral bias may not be an excessive factor in the differences we presented here. Consistent with the above reasoning, the report by Zgibor et al. suggests that specialty care was less effective for low-income patients, for whom free or easily accessible supplies are critical.

Müller et al. (8) found significant beneficial effects after 12–16 months on intensive treatment using the ASD method to compare glycemic control before and after intervention. The glycemic control of these German patients was between that of the EDC and DiabCare results at the beginning of the study. After follow-up, they had even better glycemic control than the DiabCare patients. Nicolucci et al. (19) used percentages above the upper limit of normal to compare different methods. In our study, using either of the methods, we found that DiabCare patients had lower calculated glycemic levels, although their average

HbA_{1c} was still ~8%, a value that suggests additional action, according to the American Diabetes Association (21).

In another report, the Diabetes Control and Complications Trial (DCCT) Research Group achieved their strict glycemic targets by intensive diabetes therapy, 3 shots or more daily or use of an insulin pump, frequent visits and contact with the health care team, and extensive self-monitoring (22). It is likely that the centralized and coordinated care in Hungary might help the Hungarian system approach the results of the DCCT care model by providing easy access and frequent visits to all members of the care team. In the U.S., providers are often office based and could lack these supporting professionals. In our study, it seems that even though Hungarian patients performed more of the preventive practices mentioned previously and consequently seem to achieve lower glycemic levels than EDC subjects, their glycemic control did not reach the values seen in the DCCT intensive group. EDC patients' glycemic control was comparable to that of the DCCT conventional group. (All data were collected in both studies from 6 months to 3.5 years after the DCCT was reported.)

The DCCT found a risk reduction of proliferative or severe nonproliferative retinopathy of 47% (14–67%) with a 2% difference of HbA_{1c}. In the current analysis, we observed a difference of ~0.8% in the calculated HbA_{1c} and a 47% lower prevalence of proliferative retinopathy. This observation is somewhat higher but close to the expected difference (6–27%) according to the DCCT results (22). Similarly, our observed 24% difference in the frequency of albuminuria is close to the expected 16% (8–21%) calculated according to the DCCT findings (22).

Previous studies in the U.S. showed that adherence rates to guidelines were higher among internists than among family doctors and pediatricians (23,24). Only half of the EDC patients were treated by a specialist, whereas >90% of DiabCare patients were seen by specialists.

Beckles et al. (25) reported in a telephone survey a somewhat higher rate of self-monitoring (94%) among type 1 diabetic patients than was found in EDC (77%), but they also reported a similar frequency of eye examination (Beckles 75%; EDC 71%). Peterson (26) reported that, among patients of 27 Wisconsin physicians, HbA_{1c} averaged 10.1% in type 1 diabetes (higher than the EDC baseline levels). On the other hand, type 1 diabetic patients

in the former German Democratic Republic used an average of 3 injections/day as early as 1989 and reported an HbA_{1c} of 6.3% (upper limit of normal 5.2%); 5 years later, the JEVIN Study reported an average 4.2 injections/day and, interestingly, a significantly better glycemic control in the centralized and specialized system before the reunion of the 2 Germanies (5). Nicolucci et al. (19) found similar differences in the care of type 1 diabetic patients by specialist status. These data suggest the superior role of centralized treatment by diabetes specialists in the care of type 1 diabetic patients.

In this study, we found that Hungarian patients experienced severe hypoglycemic episodes more often than the EDC patients, which is consistent with the findings in the DCCT (22).

The lower prevalence of microvascular complications among DiabCare patients in this study is likely to reflect, at least in part, the tighter glycemic control in the Hungarian patients, particularly because treatment by a diabetes specialist per se appears to have little association with the prevalence of complications in EDC patients (18). The different methods for assessing complications such as retinopathy could also have played a role; however, the sensitivity of dilated ophthalmoscopy performed by a trained ophthalmologist seems to be as sensitive (79–96%) as 3-field fundus photography (86%) (27–29). On the other hand, cataracts, legal blindness, and end-stage renal failure were defined in the same way and showed the same differences. These complications are strongly related to glycemic control (17,21,22,30,31). Furthermore, a previous comparison of EDC and EURODIAB patients found similarly a higher prevalence of albuminuria (>20 µg/min) in the EDC cohort, despite a lower prevalence of hypertension (32). Finally, the potential role of unmeasured genetic and environmental factors needs to be noted.

We found no significant difference in the prevalence of cardiovascular disease between the 2 studies. However, the absolute numbers were too small to have power to detect less than a 2- to 3-fold difference. The prevalence of hypertension was higher in DiabCare, which may partly reflect the different methodologies (32).

In conclusion, our study compared a national sample from Hungary, wherein a centralized diabetes care system was used, with a U.S. incident cohort that was defined in childhood and is now receiving community care. The Hungarian popula-

tion was more likely to have intensive insulin treatment, lower glycemic levels, and lower prevalences of microvascular complications. These differences are reduced, but not eliminated, by accounting for specialty care. These results suggest that other components of the health care structure in Hungary (including free and/or easy access to insulin pens and self-monitoring of blood glucose supplies) may be critical.

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